**Amend Ph 301.01, eff. 2-5-96 (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 301.01(a), (b)(1)-(10), (d), and (e), previously eff. 2-5-96 (Doc. #6181-B) and expired 2-5-04, cited and to read as follows:**

CHAPTER 300 LICENSING OF PHARMACISTS AND PHARMACIES

PART Ph 301 LICENSING OF PHARMACISTS BY EXAMINATION

Ph 301.01 Application.

(a) Application form Ph A-1 for licensure to practice the profession of pharmacy in New Hampshire may be obtained from and shall be filed at the office of the board, identified in Ph 103.03.

(b)

(1) Name, address, telephone number and social security number of the applicant;

(2) Date and place of birth of the applicant;

(3) Record of convictions of violations of federal, state or local liquor or drug-related laws;

(4) Pharmacy license disciplinary actions taken by any other state or licensing jurisdiction;

(5) Any felony convictions;

(6) Pharmacy college attended, graduation date and degree awarded;

(7) Practical experience before licensure as a pharmacist;

(8) A copy of the candidate's birth certificate;

(9) A recent, full face photograph of the candidate;

(10) An official final transcript sent directly from the college to the board office; and

(d) If an official final transcript is not available prior to the examination date, the candidate shall obtain a letter, sealed with the official college seal, which shall:

(1) State that the candidate has graduated;

(2) Be signed and dated on or after the date of graduation by a college official authorized to make such a certification; and

(3) Be presented to the board of pharmacy prior to admission to the examination.

(e) The photograph required by Ph 301.01 (b)(9) shall be attached to the application form in the presence of a notary public or justice of the peace.

**Amend Ph 301.02, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 301.02 intro, (a)-(d), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 301.02 Additional Requirements. In addition to any requirements imposed by statute, all candidates for a license to practice pharmacy in New Hampshire shall demonstrate that they possess the following qualifications:

(a) The candidate shall be not less than 18 years of age;

(b) The candidate shall be of good professional character as evidenced by 3 signed references, and the absence of conviction of any felony, or of a misdemeanor resulting from a violation of any drug and/or pharmacy-related law or rule;

(c) The candidate shall have graduated with a professional pharmacy baccalaureate degree or a doctor of pharmacy degree granted by a school of pharmacy, or a college of pharmacy, or a department of a pharmacy of a university;

(d) To meet the requirements of (c) above, the school, college or department of pharmacy, shall be accredited by the American Council on Pharmaceutical Education.

**Amend Ph 301.04, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 301.04 (a), (b)(1) and (b)(3), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 301.04 Scheduling of Examinations.

(a) Except as provided in(b) below, the pharmacy examination shall be administered by the board. Upon request, the board shall notify the candidate of the date of the next scheduled examination. Failure of the candidate to sit for the examination at the required time shall result in denial of the application.

(b)

(1) The examination was administered in that other state in accordance with a degree of security which was equivalent to or greater than the security employed in the administration of examinations by this board;

(3) The candidate successfully completes a practice of pharmacy jurisprudence examination administered by the board and any other requirement for licensure, within a 90-day period from the date the New Hampshire application is mailed by the board office to the candidate; and

**Adopt Ph 301.06 - 301.07, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 301.06 Notice and Election of Re-examination.

(a) Any candidate who fails to obtain the minimum required score may elect to retake the examination.

(b) All candidates shall notify the board in writing whether he/she elects to be re-examined. The request for re-examination shall be accompanied by the prescribed fee as established by Ph 301.01 (b)(11).

(c) Any re-examination permitted by this section shall be administered by the board. Upon request by the candidate, the board shall notify the candidate of the next available dates of re-examination.

Ph 301.07 Issuance or Denial of Original License.

(a) If a candidate timely files an application, complete in all respects, successfully completes all examinations required by Ph 301 and demonstrates the complete fulfillment of the requirements of these rules and RSA 318, the board shall issue a license to practice pharmacy.

(b) In the event a candidate for an original license to practice pharmacy in New Hampshire fails to meet the requirements of these rules, or RSA 318, or both, the board shall deliver to the applicant a written denial of the application, specifying in detail the requirement which the candidate failed to meet, and how the candidate is deficient.

**Amend Ph 302.01, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 302.01(a)(1)-(a)(3), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, cited and to read as follows:**

PART Ph 302 LICENSING OF PHARMACISTS BY RECIPROCITY

Ph 302.01 Reciprocity.

(a)

(1) The candidate was issued a license to practice the profession of pharmacy in that state by reason of that examination;

(2) The candidate is still duly licensed and is in good standing in that state; and

(3) All other New Hampshire pharmacist licensing requirements have been met.

**Adopt Ph 302.02, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 302.02 Application.

(a) The preliminary application for reciprocal licensure, NABP Form P provided by the National Association of Boards of Pharmacy may be obtained from the office of the board or from the National Association of Boards of Pharmacy, 700 Busse Highway, Park Ridge, Illinois, 60068, (847) 698-6227. This application shall be filed with the National Association of Boards of Pharmacy.

(b) The candidate shall file a completed application NABP Form P provided by the National Association of Boards of Pharmacy with the board.

**Amend Ph 302.03, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 302.03(a)(1)-(3), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 302.03 Contents of Reciprocity Application.

(a) The reciprocal application for a license to practice pharmacy in this state shall consist of:

(1) The National Association of Boards of Pharmacy (NABP) application Form P;

(2) A copy of the candidate's birth certificate;

(3) A recent, full-face photograph of the candidate attached to the application;

**Amend Ph 302.04, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 302.04 intro, (a) - (d), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 302.04 Requirements. In addition to any requirements imposed by statute, all candidates for licensure by reciprocity to practice pharmacy in New Hampshire shall demonstrate that they possess the following qualifications:

(a) The candidate shall be not less than 18 years of age;

(b) The candidate shall be of good professional character as evidenced by 3 signed references and the absence of conviction of any felony or of a misdemeanor resulting from a violation of any drug and/or pharmacy related law or rule;

(c) The candidate shall possess a professional pharmacy baccalaureate degree or a doctor of pharmacy degree (Pharm.D.) granted by a school of pharmacy, or a college of pharmacy, or a department of pharmacy of a university;

(d) To meet the requirements of (c) above, the school, college or department of pharmacy, shall be accredited by the American Council on Pharmaceutical Education;

**Adopt Ph 302.09, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 302.09 Reciprocity License Issuance or Denial.

(a) If a candidate timely files an application, complete in all respects and meeting the requirements of Ph 302, and demonstrate the complete fulfillment of the requirements of these rules and RSA 318, the board shall issue a license to practice pharmacy.

(b) In the event a candidate for a reciprocity license to practice pharmacy in New Hampshire fails to meet the requirements of these rules or RSA 318, or both, the board shall deliver to the candidate a written denial of the application, specifying in detail each requirement which the candidate failed to meet, and how the candidate is deficient.

**Adopt Ph 303, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

PART Ph 303 PHARMACY PERMIT OPTIONS

Ph 303.01 Licensing the Entire Store Area.

(a) The pharmacy shall include the prescription department and all other retail sections of the store.

(b) The entire pharmacy shall be equipped with a functional alarm system to prevent entry when the pharmacy is not open to the public, according to Ph 702.04.

(c) The prescription department shall not be closed while the balance of the establishment remains open.

(d) A licensed pharmacist shall be on duty at all times when the pharmacy is open to the public.

Ph 303.02 Licensing Only the Prescription Department.

(a) The pharmacy shall include only the prescription department where drugs, chemicals, medicines, prescriptions are stored, compounded and dispensed. This area shall not include the other retail sections of the store the principle business of which is not the practice of pharmacy.

(b) The prescription department described in (a), above, shall be equipped with a functional alarm system to prevent entry when the pharmacy is not open to the public according to Ph 702.04.

(c) The prescription department may be closed while the remainder of the business establishment remains open to the public. During such periods, the pharmacy shall comply with Ph 702.04.

(d) A licensed pharmacist shall be on duty at all times when the prescription department is open to the public. During any absences by the pharmacist, the prescription department shall be secured.

(e) Whenever the prescription department is closed, a sign indicating that there is no pharmacist on duty shall be conspicuously displayed in the pharmacy area. Such sign shall be composed of 3" lettering.

(f) Whenever the pharmacy is closed, prescriptions may be left via a mail slot which falls directly into the pharmacy area.

(g) The prescription mail slot:

(1) Shall be constructed so as to accept only a written or typed prescription or a notation of the prescription number for refills;

(2) Shall be no larger than 8" X 1" and designed so that prescriptions or notations, once deposited, cannot be retrieved by hand or by mechanical means; and

(3) Shall be constructed so as to deliver these prescriptions or notations directly into the prescription area for access by the pharmacist only so that they are not visible to the general public.

(h) No prescription, new or refill, shall be left with or accepted by clerks when the prescription department is closed.

(i) No finished prescriptions shall be left outside of the pharmacy area prescription department for pick-up when the prescription department is closed.

(j) No telephone prescriptions, new or refill, shall be accepted by clerks when the prescription department is closed.

(k) All drug order deliveries containing prescription drugs shall be delivered only when the prescription department is open and/or a licensed pharmacist is on the premises in order to secure such drug orders.

(l) A barrier preventing access to the prescription department by the public, shall be erected pursuant to the security requirements of Ph 702.04.

(m) The pharmacist-in-charge shall be in possession and control of keys to the prescription department. Only New Hampshire licensed pharmacists employed by the pharmacy may be designated by the pharmacist-in-charge to have keys and a list of these individuals shall be communicated to the board of pharmacy in writing whenever changes occur.

(n) All prescription departments licensed under this section shall be so equipped with a physical barrier from floor to ceiling capable of being locked and alarmed, separate from the rest of the store, to be utilized when the prescription department is not opened to the public.

Ph 303.03 Conversion of Pharmacy Permit. Conversion from licensure of the entire store to licensure of only the prescription department shall require:

(a) Plans be submitted to the board before renovations begin; and

(b) Once completed, an AMEND-A-PERMIT form, Ph A-4, pursuant to Ph 306.05, together with the prescribed fee of $150., shall be submitted to the board. This form shall be processed and a new pharmacy permit issued before the pharmacy department may open different hours from the remainder of the establishment.

**Adopt Ph 304.01, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, cited and to read as follows:**

PART Ph 304 ORIGINAL PHARMACY PERMIT APPLICATION

Ph 304.01 Obtaining and Filing a Permit Application. Applications for a permit to operate a pharmacy in New Hampshire may be obtained from, and shall be filed at, the board office, identified in Ph 103.03.

**Amend Ph 304.02, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 304.02 (a) - (d), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 304.02 Application Contents.

(a) The applicant for a permit to operate a pharmacy in New Hampshire, shall supply on form Ph A -3, at least the following information:

(1) Type of pharmacy;

(2) Name and home address of licensing pharmacist;

(3) Name of pharmacy;

(4) Identification of ownership,

(5) Pharmacy operation hours;

(6) Name, license number, hours worked for all pharmacists employed;

(7) Approximate value of prescription drug inventory;

(8) List of persons having keys/access to the pharmacy; and

(9) Signature of the pharmacist-in-charge and date signed.

(b) The applicant shall also submit scale drawings of the pharmacy, detailing usage of all space.

(c) It shall be the responsibility of the applicant to supplement the application with any certificates, affidavits, plans, documents, or other information sufficient to show full compliance with all of the requirements of part Ph 304.

(d) If the applicant is a corporation, or if the pharmacy will be operated under a corporate name, a certificate from the secretary of state attesting to the documents creating the corporate person and any amendment(s) thereof to the certificate of incorporation, or authorizing it to do business in the state of New Hampshire under the corporate name.

**Adopt Ph 305 - 306, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

PART Ph 305 ORIGINAL PERMIT PROCEDURE

Ph 305.01 Original Permit Conference.

(a) In addition to all requirements set forth in the statutes and elsewhere in this chapter, each applicant applying for a permit to operate a pharmacy in New Hampshire shall appear before the board for an informal conference to review the responsibilities of the pharmacist-in-charge and to determine if, in the opinion of the board, issuance of the permit would be in the best interest of public health and welfare.

(b) If the owner is not the pharmacist-in-charge, then the owner or an officer of the corporation, or the district manager, as well as the anticipated pharmacist-in-charge shall appear before the board.

Ph 305.02 Site Inspection for Original Permit.

(a) Following the applicant's conference, the proposed site shall be inspected by one or more board members or compliance inspectors to determine if the premises are secure and suitable, according to the provisions of Ph 702, for the operation of a pharmacy and that the required professional library material, according to Ph 702.07 (7) (8), is available.

(b) Within the 60 day period after the issuance of the temporary permit as required by Ph 305.03, an inspector or a board member or both shall inspect the pharmacy. The full operation of the pharmacy shall be examined for compliance with federal and state statutes and rules governing the practice of pharmacy to ensure public protection.

Ph 305.03 Issuance and Denial of Original Permit.

(a) Providing that, the premises are suitable, according to Ph 305.02 (a), for the operation of a pharmacy and the applicant has met all other requirements of these rules and RSA 318, the applicant shall be granted a temporary permit which shall expire in 60 days. The temporary permit shall authorize the operation of a pharmacy only in the location and only under the name specified in the permit and shall authorize the pharmacist-in-charge to buy, possess and dispense prescription drugs, chemicals and pharmaceuticals.

(b) If an applicant files an application, complete in all respects and demonstrates the complete fulfillment of all of the requirements of these rules and RSA 318, the board shall issue a permit which shall authorize the operation of a pharmacy only in the location, and only under the name, specified in the permit.

(c) After consideration of the application and the report of the primary site inspection, the board shall notify the applicant in writing of all deficiencies in the application which, in the absence of correction, shall result in the denial of the application. The applicant shall, within 20 days of the date of the notice of deficiency, deliver to the board either documents evidencing the correction of those deficiencies, or a written request for an appeal before the board. In the absence of a timely filing of either documentation or a request for an appeal, the application shall, without further action or notice by the board, be denied effective as of the expiration of 20 days after the date of the notification of deficiency.

PART Ph 306 PERMITS - CHANGES IN SUPPORTING DATA

Ph 306.01 Pharmacy Ownership Transfer. A transfer of ownership shall include any of the following:

(a) The sale of the pharmacy;

(b) The addition or deletion of one or more partners in a partnership;

(c) The death of a singular owner; or

(d) The change of ownership of the controlling interest of the voting stock of a corporation since the issuance of the license or last renewal application.

Ph 306.02 Reporting Changes. The person to whom a permit to operate a pharmacy in New Hampshire has been issued shall, within 15 days of that person's discovery of a change in any of the data contained in the application for an original or renewal permit, report that change to the board in writing. An original permit application form shall be filed in addition to the written notice when the location or ownership of the pharmacy is changed. An amended application form shall be filed in addition to the written notice when the pharmacist-in-charge or the name of the pharmacy or both is changed.

Ph 306.03 Change in Pharmacy Name or Location - Prohibited. No person shall operate a pharmacy under a name, or at a location, different from the name and location contained in the permit issued pursuant to Ph 304, or an amendment of that permit issued pursuant to Ph 305.

Ph 306.04 Renovations. Plans for any at any time after an original permit is issued shall be filed with the board for review and approval before proceeding with such changes.

Ph 306.05 Amend Permit Application Contents and Where Filed.

(a) Each applicant for amending a pharmacy permit for the purpose of a change of pharmacist-in-charge, a pharmacy name change or a licensed area change shall make application on an Amend-A-Pharmacy Form Ph A-4.

(b) Applicants filing a form Ph A-4 shall supply at least the following:

(1) The type of change requested;

(2) The names of the prior and current/new pharmacist-in-charge;

(3) The names of pharmacist(s) on staff;

(4) The date changes will be effective;

(5) The pharmacy's hours;

(6) A record of convictions or any findings of violations of pharmacy or drug related law against any individual or corporation named in this application; and

(7) Signature of the pharmacist-in-charge and date signed.

(c) The application shall be filed at the board office identified in Ph 103.03 and submitted with the prescribed fee of $150.

Ph 306.06 Issuance and Denial of Amended Permits.

(a) If a registrant shall file an application, complete in all respects, and shall have demonstrated the complete fulfillment of all of the requirements of this part, the board shall issue an amended permit. Upon receipt of this new permit, the licensee's existing permit shall be returned to the board office identified in Ph 103.03. Upon receipt of that amended permit the registrant shall operate the pharmacy under that amended permit.

(b) After consideration of the application, the board shall notify the licensee in writing of any deficiencies in the application. The licensee shall, within 20 days of the notice of deficiency, deliver to the board either documentation evidencing the correction of those deficiencies, or file a written request for an appeal before the board. In the absence of a timely filing of either that documentation or a request for appeal, the application, shall, without further action or notice by the board, be denied effective as of the expiration of 20 days after the date of the notification of deficiency.

**Adopt Ph 307.01 - 307.02, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

PART Ph 307 RENEWAL AND REPLACEMENT PERMITS

Ph 307.01 Renewal Permits Required. The person to whom a permit to operate a pharmacy in New Hampshire has been issued shall renew that permit whenever any of the following occur:

(a) The pharmacist-in-charge terminates his or her status as the pharmacist-in-charge;

(b) The license of the pharmacist-in-charge is suspended or revoked;

(c) Ownership of the pharmacy for which the permit was issued is changed;

(d) The location of the pharmacy is changed; or

(e) The calendar year ends.

Ph 307.02 Renewal Application Where Obtained and Filed. Applications for the renewal of a permit to operate a pharmacy in New Hampshire may be obtained from, and shall be filed at the board office.

**Amend Ph 307.03, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 307.03 (b), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 307.03 Renewal Application Contents and When Filed.

(b) Renewal applications shall be filed with the board in accordance with the following schedule:

(1) When the renewal is required pursuant to Ph 307.01 (a) through (d), not later than 60 days prior to the date upon which those causes shall be effective, or as soon thereafter as the licensee discovers, or with reasonable diligence, should have discovered, the existence of the cause; or

(2) When the renewal is required pursuant to Ph 307.01 (e), not later than the 15th day of December of each year.

**Adopt Ph 307.04, 307.05, 307.06, 308, and 309, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 307.04 Renewal Application Deficiencies. The board shall notify the applicant in writing as to how the application for renewal is deficient. The applicant may, within 10 days after the date of the notice of deficiency, correct the deficiency or file with the board a written request for an appeal.

Ph 307.05 Issuance and Denial of Renewal Permit.

(a) If an applicant shall timely file an application, complete in all respects, and shall demonstrate the complete fulfillment of all the requirements of these rules and RSA 318, the board shall issue a renewal permit.

(b) An application failing to meet the requirements of these rules and RSA 318 shall, after the notice and opportunity for hearing provided in Ph 307.04, be denied.

Ph 307.06 Replacement Permit Application and Contents.

(a) The holder of a current permit to operate a pharmacy in New Hampshire, whose permit has been lost or destroyed shall apply for a replacement permit within 15 days after the date the

licensee discovers, or with reasonable diligence, should have discovered, the loss or destruction of the permit. There shall be no form prescribed for an application for a replacement permit.

(b) The request for a replacement permit shall:

(1) Be in writing;

(2) Contain the number of the current permit held by the applicant, if known;

(3) Be accompanied by the remains, if any, of the permit for which a replacement is sought;

(4) Be accompanied by the prescribed fee of $50.; and

(5) Be filed at the board office.

PART Ph 308 REVOCATION AND SUSPENSION

Ph 308.01 Effect of Revocation.

(a) The revocation of a pharmacy permit shall permanently withdraw the authority to operate a pharmacy in New Hampshire.

(b) A subsequent permit may be obtained only by:

(1) Complying with all of the requirements of RSA 318 and these rules regarding the original licensing of pharmacies;

(2) Paying all penalties assessed in connection with the cause for revocation; and

(3) By demonstrating that the cause for revocation does not exist at the time of the subsequent application.

Ph 308.02 Effect of Suspension.

(a) The suspension of a pharmacy permit shall temporarily withdraw the authority to operate a pharmacy in New Hampshire until the time specified in the order of suspension.

(b) The authority to operate a pharmacy in New Hampshire shall be recovered only by;

(1) Complying with all of the requirements specified in the order of suspension;

(2) Complying with all of the requirements of RSA 318 and these rules regarding the renewal of a pharmacy permit; and

(3) Paying all penalties assessed in connection with the cause for suspension.

Ph 308.03 Voluntary Surrender When Permitted.

(a) Any person holding a pharmacy permit may voluntarily return that permit to the board.

(b) The return of such permit shall be accompanied by the licensee's signed, written statement as to why the permit is being voluntarily returned to the board.

(c) The voluntary surrender of a permit to operate a pharmacy in New Hampshire shall serve to withdraw the authority for the licensee to operate that pharmacy in New Hampshire.

(d) Voluntary surrender of a permit to operate a pharmacy in New Hampshire shall not be permitted if there exists, at the time the permit is presented to the board, any cause for involuntary revocation or suspension of the licensee's permit to operate a pharmacy, unless the licensee presenting the permit shall state in writing that the voluntarily surrendered permit is in lieu of proceedings for the involuntary revocation or suspension of the permit to operate a pharmacy in New Hampshire.

Ph 308.04 Hearing. Except as authorized by statute or these rules, a permittee to operate a pharmacy in New Hampshire shall not be disciplined except after notice and opportunity for hearing provided by Ph 200.

Ph 308.05 Other Licensing Fees. The annual licensing fee for federally funded clinics under the direction of the department of health and human services shall be $50.

Ph 308.06 Other Examination Fees. The fee for the administration of the pharmacy practice jurisprudence examination to physician's assistants shall be $50.

## PART Ph 309 STANDARDS OF PRACTICE FOR MANUFACTURERS, WHOLESALERS AND DISTRIBUTORS

Ph 309.01 License Required.

(a) No person shall manufacture or act as a wholesale distributor of prescription drugs or prescription devices without first obtaining a license to do so from the board according to RSA 318:51-a. No license shall be issued or renewed for a manufacturer or wholesale drug distributor unless the same shall be operated in a manner prescribed by law and according to the rules adopted by the board of pharmacy with respect thereto.

(b) Separate licenses shall be required for each manufacturing and distribution site owned or operated by a manufacturer or wholesale distributor. Provided however, that an agent or employee of any licensed manufacturer or wholesale distributor shall not be required to be licensed under this section and may lawfully possess prescription drugs and devices if he is acting in the usual course of his business or employment.

(c) The board shall provide, on an annual basis, a license renewal form to all licensed manufacturers and wholesale distributors of prescription drugs and devices.

(d) The prescribed fee for original and annual renewal licenses for manufacturers and wholesale distributors of prescription drugs and devices shall be $250.

Ph 309.02 Obtaining and Filing a License Application. Applications for licensure of manufacturers, wholesalers and distributors may be obtained from, and shall be filed at, the board office, identified in Ph 103.03.

Ph 309.03 Application Contents. The applicant for licensure shall supply, on form Ph A-4, at least the following information:

(a) Name of the company;

(b) The address of the actual location where manufacturing, wholesaling and distribution occurs;

(c) Identification of ownership; and

(d) Name and address of the person responsible for licensing.

Ph 309.04 Storage Conditions. All facilities at which prescription drugs are repackaged, wholesaled, stored, held, sold, offered for sale, exposed for sale, or kept for sale shall provide storage areas that ensure proper lighting, ventilation, temperature, sanitation, humidity, equipment, and security conditions. All prescription drugs or chemicals shall be stored at appropriate temperatures per label requirements or in compliance with official United States Pharmacopeia (USP) compendium requirements to help ensure that the identity, strength, quality, and purity of the products are not affected. If no temperature requirements are listed, prescription drugs may be stored at room temperature in compliance with U.S.P. definition for room temperature. A separate storage section shall be provided for prescription drugs that are deteriorated, outdated, misbranded, or otherwise adulterated.

Ph 309.05 Facilities.

(a) All buildings in which prescription drugs are wholesaled, repackaged, stored, held, sold, offered for sale, exposed for sale, or kept for sale shall be of suitable size, construction, and location to facilitate cleaning and maintenance.

(b) Buildings shall meet all applicable federal, state, and local standards. A facility shall not be located in a residence. All facilities shall be located in an area that is commercially zoned.

(c) A wholesale drug distribution facility shall notify the local police department or other appropriate law enforcement agency that it is a distributor of prescription drug products and controlled substances.

Ph 309.06 Security.

(a) Each wholesale drug distribution center shall be equipped with an internal alarm system to detect entry after hours. The alarm system shall be of the type that transmits a signal directly to a central station protection company, to a local or state police agency that has a legal duty to respond, a 24 hour control station operated by the wholesale drug distributor.

(b) Manufacturers and wholesale drug distributors shall ensure that all access from outside their premises is secure. This shall include, but not be limited to, the installation of adequate lighting at the outside perimeter of the premises.

(c) Internal security policies shall be developed to provide protection against theft by personnel.

Ph 309.07 Recordkeeping.

(a) Inventories and other records of transactions regarding the receipt and disposition of prescription drugs shall be maintained and made available for inspection by the board's inspectors for a period of 2 years.

(b) Records may be kept at a central location rather than at each distribution center, but records shall be made available for inspection within 72 hours of request by the board's inspectors.

Ph 309.08 Inspections.

(a) Inspections shall be performed by the board's inspectors and be conducted at the request of the board.

(b) Inspections shall be conducted during normal business hours, and notification of inspections shall be given no less than 48 hours in advance.

(c) Information that is considered to contain trade secrets or which might be proprietary in nature shall be protected from outside disclosure.

Ph 309.09 Written Policies and Procedures.

(a) Written policies and procedures shall be developed by management personnel to assure that the manufacturer and wholesale drug distributor prepares for, protects against, and handles crisis situations that affect the security or operation of the facility. Such crises may include fires, floods, or other natural disasters, and situations of local, state or national emergency.

(b) Written policies and procedures described in (a) above shall also provide for:

(1) The management and correction of all errors or inaccuracies in inventories;

(2) The assurance that any outdated stock, or any stock with an expiration date that, in the wholesale drug distributor's view, does not allow sufficient time for repacking or resale, shall be prepared for return to the manufacturer or otherwise destroyed; and

(3) The control over the shipping and receiving of all stock within the operation.

(c) A copy of the policies and procedures, or sections thereof, shall be made available to the board upon request.

Ph 309.10 Returned Goods. A wholesale operation shall maintain a procedure for the proper handling and disposal of returned goods.

Ph 309.11 Handling Recalls.

(a) A wholesale operation shall maintain a written policy for handling recalls and withdrawals for products.

(b) Policies required by (a) above shall cover all recalls and withdrawals of prescription drug products due to:

(1) Any voluntary action on the part of the manufacturer;

(2) The direction of the Food and Drug Administration, or any other federal, state or local governmental agency; and

(3) Replacement of existing merchandise with an improved product or new package design.

Ph 309.12 Responsibility for Operation. A wholesale drug distribution operation shall maintain a list of principals and persons in charge including officers, directors, or primary stockholders and their qualifications.

Ph 309.13 Compliance with State and Federal Law.

(a) All manufacturers, wholesalers and distributors shall comply with all applicable state and federal laws and regulations.

(b) All manufacturers, wholesalers and distributors, doing business in New Hampshire, shall, before shipping or distributing any prescription drug, verify that the recipient is properly licensed to receive and possess such drugs.

(c) All manufacturers, wholesalers and distributors, licensed and doing business in the state of N.H., shall not provide unsolicited controlled drug samples to licensed practitioners.

(d) A manufacturers license shall allow for the direct wholesaling or distribution of such drugs to other licensed or authorized recipients.

(e) A duly authorized agent of a manufacturer, wholesaler or distributor licensed in this state, may possess and distribute potent or prescription drugs to individuals who may lawfully possess such drugs as may be necessary to further the licensed activity of the manufacturer, wholesaler or distributor.

(f) Indirect sale or distribution shall include, but not be limited to:

(1) Solicitation, in this state, by manufacturers, wholesalers or distributors sales representatives;

(2) Telephone solicitations to customers located in this state by manufacturers, wholesalers or distributors sales representatives;

(3) Solicitation of customers located in this state by mail or by the use of media advertising which has a significant circulation in the state of New Hampshire.

Ph 309.14 Violations.

(a) No manufacturer or wholesaler shall distribute prescription drugs directly to a consumer or a patient, or operate in such a manner as to endanger the public health.

(b) Any person who manufacturers, wholesales, or otherwise distributes prescription drugs, according to RSA 318:51-a and the provisions of Ph 309, shall be subject to disciplinary action as provided in RSA 318:29.

**Adopt Ph 401.01, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

CHAPTER Ph 400 CONTINUED STATUS

PART Ph 401 RENEWAL AND REPLACEMENT LICENSES

Ph 401.01 Obtaining and Filing Renewal Applications. Applications for the renewal of a license to practice pharmacy in New Hampshire may be obtained from, and shall be filed at, the board office.

**Amend Ph 401.02, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 401.02 (a) and (b), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 401.02 Renewal Application Contents and Filing Deadline.

(a) Applications for renewal of a license to practice pharmacy in New Hampshire under RSA 318 shall be made on a Pharmacist Licensure Renewal Form Ph A-2.

(b) Each applicant shall provide the following on Form Ph A-2 regarding himself/herself:

(1) Name, residence address, home telephone number, original pharmacy license, social security number and date of birth;

(2) Name of current employer, address of employment site, hours worked per week;

(3) Record of charges, convictions, indictments for violations of Federal, State, local drug or pharmacy related law or regulations;

(4) Current licensure in other states;

(5) Report of continuing education; and

(6) Applicant's signature and date.

**Adopt Ph 401.03, 401.04, and 401.05, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 401.03 Renewal Application Deficiencies. Within 5 days of receipt at the board office, the board shall notify the applicant in writing if the renewal application is deficient. The applicant may then correct the deficiency or file with the board a written request for a hearing before the board.

Ph 401.04 Renewal License Issuance and Denial.

(a) Issuance. If an applicant timely files an application, complete in all respects, and demonstrates the complete fulfillment of all the requirements of these rules and RSA 318, the board shall issue a renewal license to practice pharmacy.

(b) Denial. An application failing to meet the requirements of these rules or RSA 318, or both, shall, after the notice and opportunity for hearing provided in Ph 401.03, be denied.

Ph 401.05 Duplicate/Replacement Original Certificate of Licensure or Renewal License - Issuance.

(a) If for an original Certificate of Licensure the applicant shall:

(1) Submit a written request, signed by the pharmacist, to the board for replacement; and

(2) Provide payment of the prescribed fee which shall be $50.

(b) If for an annual Renewal License the applicant shall:

(1) Submit a written request, signed by the pharmacist, to the board for a duplicate or replacement; and

(2) No fee shall be assessed for a duplicate or replacement renewal license.

**Amend Ph 401.06, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting 401.06 (a) - (d) and (f) - (g), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 401.06 Reinstatement. A pharmacist whose license to practice pharmacy in this state has been suspended, revoked, voluntarily surrendered or allowed to lapse for a period of 12 months or more shall:

(a) File a reinstatement application with this board which shall include at least the following:

(1) Name, address and telephone number of the applicant;

(2) Social security number;

(3) Date of birth; and

(4) Current employment information.

(b) Pay the reinstatement fee of $200.

(c) Pay all yearly renewal fees in arrears.

(d) Submit original certificates of attendance/participation in accredited/approved continuing pharmaceutical education courses/programs for a minimum of 15 hours, of which at least 5 hours shall be earned in a didactic setting. All such continuing education shall have been earned in the period 12 months immediately preceding the date of application for reinstatement.

(f) If the pharmacist has not held a license to practice pharmacy in this state for a period of 2 years or more, the applicant shall provide:

(1) Notarized affidavit(s) documenting the pharmacist's pharmacy experience during the 2 years immediately preceding the date of his/her application for reinstatement; and

(2) Proof of status of licensure in all states that the pharmacist has been licensed in.

(g) If the pharmacist has not held a license to practice pharmacy in this state for a period of 5 years or more and has not practiced pharmacy in any other state, the board might additionally require the completion of a period of pharmacy practice internship prior to reinstatement.

**Adopt Ph 401.07, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 401.07 Gold Certificates.

(a) The board of pharmacy shall issue a gold certificate to any pharmacist who has been regularly licensed as a pharmacist for 50 consecutive years.

(b) Gold certificates shall be distinctive in coloration and text from other pharmacist licenses issued by the board, and shall be designed to appropriately recognize each recipient pharmacist for his/her half-century of professional practice.

(c) A gold certificate shall be a one-time issuance of honorary nature and confer no right to practice pharmacy upon the recipient.

(d) The awarding of gold certificates shall be made by the board of pharmacy without charge to the recipient.

**Adopt Ph 402, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

PART Ph 402 DISCIPLINARY MATTERS

Ph 402.01 Effect of Revocation.

(a) The revocation of a pharmacist license shall permanently withdraw the authority to practice pharmacy in New Hampshire.

(b) A subsequent license may be obtained only by:

(1) Complying with all of the requirements of RSA 318 and these rules regarding the original licensing of pharmacists;

(2) Paying all penalties assessed in connection with the cause for revocation; and

(3) Demonstrating that the cause for revocation does not exist at the time of the subsequent application.

Ph 402.02 Effect of Suspension.

(a) The suspension of a pharmacist license shall temporarily withdraw the authority to practice pharmacy in New Hampshire until the time specified in the order of suspension.

(b) The authority to practice pharmacy in New Hampshire shall be recovered only by:

(1) Complying with all of the requirements specified in the order of suspension;

(2) Complying with all of the requirements of RSA 318 and these rules regarding the renewal of a license to practice pharmacy in New Hampshire; and

(3) Paying all penalties assessed in connection with the cause for suspension.

Ph 402.03 Voluntary Surrender of License.

(a) Any person holding a pharmacist license may voluntarily surrender that license by returning it to the board accompanied by a signed letter stating that the pharmacist intends to permanently surrender his or her license.

(b) The surrender shall be effective upon receipt and shall immediately preclude the pharmacist from practicing pharmacy in New Hampshire.

(c) A voluntary license surrender, standing alone, shall not prevent the pharmacist from subsequently reapplying for a license.

(d) The voluntary surrender of a license shall have no effect upon the board's authority to:

(1) Investigate violations of the pharmacy laws or the rules of the board by a person licensed at the time the alleged violation occurred; or

(2) Impose disciplinary sanctions based on past conduct which could affect the ability of the former licensee to reapply for a license at a later date.

(e) A voluntary license surrender during the pendency of a disciplinary proceeding shall be recorded in the board's files as "surrendered during disciplinary proceeding."

(f) Nothing in this section shall prohibit the board and a licensee from entering into a settlement agreement or a consent decree relative to any alleged violation of the pharmacy laws or the rules of the board.

Ph 402.04 Hearing. Except as authorized by statute or these rules, a licensee shall not be disciplined except after notice and opportunity for hearing.

**Amend Ph 403.01, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 403.01 (c) – (h), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

(c) "AMA category I programs" means all programs accepted by the American Medical Association in category I.

(d) "Continuing education" means accredited or approved post-licensure pharmacy education designed to maintain professional competence in the practice of pharmacy, improve professional skills, and preserve pharmaceutical standards for the purpose of protecting the health and welfare of the citizens in the state of New Hampshire. Continuing education includes study in one or more of the general areas of the properties and actions of drugs and dosage forms, etiology, characteristics and therapeutics of the disease state, socio-economic and legal aspects of health care.

(e) "Continuing education advisory council" (CEAC) means a group of individuals appointed by the board of pharmacy to serve in an advisory capacity on continuing education.

(f) "Continuing education unit" (CEU) means 10 contact hours of participation in accredited or board approved continuing education courses/programs.

(g) "Certificate of accredited/approved CEU's" means a document, issued to a particular pharmacist by an accredited or approved provider certifying that the pharmacist has satisfactorily completed a specified number of CEU's. Such certificates include a unique program identification number issued by the accrediting/approving provider.

(h) "In-state approved provider" means an individual, institution, organization, association, corporation or agency located in the state of New Hampshire in no manner affiliated with any manufacturer or distributor of supplies or services used in the practice of pharmacy, who is approved by the board of pharmacy to provide continuing pharmacy education according to 403.13.

**Amend Ph 403.02, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 403.02 (a) - (f), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 403.02 Renewal Requirements.

(a) The board of pharmacy shall not issue licensure renewals unless the pharmacist indicates on the renewal application, and under penalty of unsworn falsification, that he/she has completed the minimum required hours of accredited/approved continuing pharmaceutical education courses/programs according to Ph 403.02(d). An incomplete renewal application shall be returned to the applicant.

(b) Continuing education shall be required of all licensed, active or inactive pharmacists who apply for license renewal.

(c) Pharmacists submitting applications for the first annual licensure renewal after initial New Hampshire licensure shall be exempt from the continuing education requirements.

(d) All pharmacists licensed in New Hampshire shall acquire 1.5 CEU's during the 12 months immediately preceding the license renewal date of January 1st. At least 0.5 CEU's shall be earned in a didactic setting.

(e) Continuing education credits shall not be recognized for any repeat program attended or completed. Repeat programs shall be identified as any program, didactic or correspondence, which carries the same ACPE, CME or any board of pharmacy program identification number.

(f) The pharmacist shall retain all certificates and/or other documented evidence of participation in an approved/accredited continuing education program/course for a period of at least 3 years. Such documentation shall be made available to the board for random audit and/or verification purposes.

**Adopt Ph 403.03 - 403.13, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 403.03 Excess CEU's. Excess CEU's earned in one licensure period shall not be carried forward into the new licensure period for the purpose of fulfilling that year's continuing education prerequisite for licensure renewal.

Ph 403.04 CEU's from Other States. The board of pharmacy shall accept comparable continuing education units which have been approved by other boards of pharmacy provided they meet or exceed the requirements as set forth in Ph 403.

Ph 403.05 Credit for Instructors of Continuing Education.

(a) Any pharmacist, whose primary responsibility is not the education of health professionals, who leads, instructs or lectures to groups of nurses, physicians, pharmacists or others on pharmacy related topics in organized continuing education or in-service programs, shall be granted continuing education credit for such time expended during actual presentation.

(b) Any pharmacist whose primary responsibility is the education of health professionals shall be granted continuing education credit only for time expended in leading, instructing, or lecturing to groups of physicians, pharmacists, nurses or others on pharmacy-related topics outside his/her formal course responsibilities in a learning institution.

(c) Credit for presentation of in-service training programs or other lectures shall be granted only once for any given program or lecture.

(d) A maximum of 4 hours in this category may be applied toward fulfilling the total continuing education yearly requirements. However, these hours shall not be considered in fulfilling the didactic requirements as set forth in Ph 403.02(d).

Ph 403.06 Postgraduate Pharmacy Curricula.

(a) A pharmacist who matriculates in a postgraduate pharmacy curriculum or post graduate pharmacy program shall be awarded CEU's for satisfactory completion of each course within said curriculum or program.

(b) The course work for which CEU credit shall given pursuant to (a) above shall provide instruction in one or more of the following areas of study:

(1) Pharmacy;

(2) Pharmaceutical calculations;

(3) Pharmaceutical chemistry;

(4) Pharmacology;

(5) Therapeutics;

(6) Pharmacy management;

(7) Pharmaceutical jurisprudence; or

(8) Other course work related to the pharmaceutical sciences.

Ph 403.07 Audio/Visual Continuing Education.

(a) Continuing education credit may be claimed for the completion of home study audio and/or video cassette tape programs/courses, provided that such programs require the completion of a written exam by the pharmacist to be scored by the provider of such programs.

(b) Audio/visual continuing education programs, including satellite transmissions, which provide for group discussion and include a facilitator shall, be allowed as didactic programming.

Ph 403.08 Waiver. The board shall waive the continuing education requirements for such hardships as illness or incapacity. Written request for waiver shall be submitted to the board for consideration.

Ph 403.09 Military Personnel. Military personnel or spouses shall not be exempt from the continuing education requirements, because correspondence programs/courses are available, but shall be exempt from the didactic requirement if assignment is in a foreign country.

Ph 403.10 Reinstatement. Any pharmacist desiring reinstatement of licensure shall show evidence of completion of at least 1.5 CEU's, according to Ph 403.02(d) and earned in the 12 months immediately preceding the date of application for reinstatement.

Ph 403.11 Penalty. Any pharmacist who alters, forges, or intentionally falsifies, or causes to be altered, forged, or falsified any information, documents, or records required to be kept or submitted by this rule shall be subject to disciplinary action under RSA 318:29(II). Falsification of records shall constitute misconduct.

Ph 403.12 In-State Approved Providers of Continuing Pharmacy Education.

(a) An individual, institution, organization, association, corporation or agency located in the state of New Hampshire desiring to be an in-state provider of continuing pharmacy education shall notify the board in writing subject to the criteria set forth in Ph 403.12 (d)(1)-(10).

(b) Approval of in-state providers shall be valid for a period of 2 years from date of approval after which time re-application shall be necessary.

(c) In-state providers who desire to become approved by the board shall demonstrate ability and willingness to offer quality continuing pharmacy education in a responsible manner and shall adhere to the provisions of (d), below.

(d) Providers shall comply with the following:

(1) The provider shall designate a responsible person for the administration of the continuing pharmacy education program and liaison with the CEAC and the board;

(2) Providers shall award continuing pharmacy education credit to successful participants in terms of CEU's;

(3) The provider shall maintain a list of successful participants for each program provided for a period of not less than 3 years;

(4) The list required by (3) above shall be made available to the CEAC and the board on request;

(5) The provider shall award to each successful participant a certificate containing at least the following information:

a. The name of the provider;

b. The completion date of the continuing education program;

c. The name of the participant;

d. The title of the program;

e. The number of CEU's the program has been assigned; and

f. The board of pharmacy program identification number;

(6) All programs shall be referenced as "didactic" or "correspondence" in nature;

(7) Providers shall present their participants with a statement of goals and objectives prior to each continuing pharmacy education program and involve their participants in identifying their own educational needs;

(8) Providers shall develop and employ evaluation techniques that will assess the effectiveness of the continuing pharmacy education offerings and the level of fulfillment of the stated objectives with the goal of continual improvements;

(9) Providers shall utilize an evaluation mechanism for the purpose of allowing each participant to assess his/her achievement of personal objectives; and

(10) Providers shall assign an identification number to every program presented according to the numbering system designated by the board of pharmacy.

(e) Continuing education programs presented by in-state approved providers need not be submitted to the CEAC for review and approval by the board.

(f) In-state approved providers of continuing pharmacy education shall publicize programs and/or coursework by referencing endorsement by the board only as follows: "This program is approved by the New Hampshire Board of Pharmacy for _____ CEU's of continuing pharmacy education". Programs shall also be referenced as "didactic" or "correspondence" in nature.

(g) Board approval of in-state provider shall be revoked following notice and opportunity to be heard upon a finding that the provider has engaged in fraud or dishonesty or is no longer in compliance with one or more of the criteria of (d) above.

Ph 403.13 Continuing Education Advisory Council Membership.

(a) The advisory council shall consist of not less than 6, nor more than 10 members, at least one of whom shall be a member of the board.

(b) The term of appointment shall be for 3 years and shall be served until the expiration date or until a successor has been named. Should a vacancy occur, a successor shall be appointed to serve the unexpired term.

(c) The advisory council shall submit all recommendations to the board for its implementation and/or approval.

(d) It shall be the duty of the advisory council to:

(1) Elect from its membership a chairman and a secretary annually;

(2) Recommend to the board the standards and specifications required of programs/courses which might be acceptable for board approval in fulfilling continuing education requirements;

(3) Recommend programs which meet the standards and specifications adopted;

(4) Recommend the number of CEU's granted for the satisfactory completion of approved programs; and

(5) Provide such other assistance to the board necessary in the implementation and maintenance of the continuing education licensure renewal prerequisite.

(e) The advisory council shall meet a sufficient number of times annually to properly perform its functions.

(f) The advisory council quorum shall be equal to the majority of the council membership.

**Adopt Ph 404, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

PART Ph 404 STANDARDS FOR COMPOUNDING AND DISPENSING STERILE PHARMACEUTICALS

Ph 404.01 Environment. Pharmacies engaged in the practice of compounding and dispensing of parenteral solutions shall have a designated area for the preparation of sterile products for dispensing which shall:

(a) Be in compliance with Federal Standard 209E,"Clean Room and Work Station Requirements," Controlled Environment, as approved by the Commission, Federal Supply Service, General Services Administration;

(b) Meet the standards for Class 100 HEPA filtered air such as a laminar air flow hood or clean room which shall:

(1) Have cleanable surfaces, walls and floors;

(2) Be ventilated in a manner not interfering with laminar air flow;

(3) Provide for an annual certification of the laminar air flow hood in compliance with Federal Standard 209D;

(4) Be arranged in such a manner that the laminar-flow hood is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral solutions;

(5) Provide for sufficient space, well separated from the laminar-flow hood area, for the storage of bulk materials, equipment and waste materials;

(6) Include a sink with hot and cold running water within the parenteral solution compounding area; and

(7) Include a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all materials requiring refrigeration.

(c) Provide for the storage of bulk solutions and/or devices stored in designated areas outside of the licensed pharmacy area, provided that such areas have been authorized by the board, are secure and accessible only to authorized personnel.

(d) The annual certification in (b) (3) above, shall be retained for at least 3 years.

Ph 404.02 Laminar Hood. In all pharmacies preparing parenteral cytotoxic agents, all compounding shall be conducted within a certified Class II Type A or Class II Type B vertical laminar air flow hood with bag-in, bag-out design. The pharmacy shall ensure that contaminated air plenums that are under positive air pressure are leak tight.

Ph 404.03 Labelling. In addition to existing labelling requirements, parenteral product labels shall include:

(a) The telephone number of the pharmacy;

(b) The name and concentrations of all ingredients contained in the parenteral products including primary solution;

(c) The instructions for storage and handling; and

(d) A special label which states: "Chemotherapy-Dispose of Properly" for cytotoxic agents.

Ph 404.04 Records.

(a) Pharmacies engaged in the practice of compounding and dispensing of parenteral solutions shall have on the premises or readily accessible, a patient record for each patient being treated with parenteral therapy.

(b) In addition to existing recordkeeping requirements, the following records shall be maintained in the pharmacy:

(1) A record of the furnishing of all prescriptions and medical supplies;

(2) Information relevant to the patient's parenteral therapy, which shall include but not be limited to:

a. The patient's name, age, sex and address;

b. The telephone number of location where patient is receiving parenteral therapy;

c. The primary diagnosis related to need for prescribed therapy/secondary diagnosis;

d. A summary of the most recent hospitalization and/or previous history; and

e. Medication history, including current diet/medication regimen and drug/food allergies;

(3) Progress notes documenting contact with the patient or physician relative to parenteral therapy; and

(4) Laboratory data relevant to parenteral therapy.

Ph 404.05 Dress Code. Persons preparing cytotoxic agents shall wear gowns and gloves.

Ph 404.06 Consultation. Consultation by the pharmacist shall be available to the patient and/or primary caregiver concerning proper use of parenterals and related supplies furnished by the pharmacy.

Ph 404.07 Training. The managing pharmacist shall ensure all pharmacists engaging in compounding parenteral solutions shall have training or demonstrated previous training in the safe handling and compounding of parenteral solutions, including cytotoxic agents.

Ph 404.08 Policies and Procedures.

(a) Pharmacies providing parenteral services shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The procedures shall include cleanup of spills and shall be in conformance with the requirements established by local public health departments. The pharmacy shall ensure the return of such materials or shall communicate the proper destruction of such materials to the caregiver.

(b) Pharmacies engaged in the practice of compounding and dispensing parenteral solutions shall have written policies and procedures which describe the methods and approaches employed by the pharmacy in all areas of the pharmacy's parenteral therapy services.

Ph 404.09 Quality Assurance.

(a) The pharmacist-in-charge shall develop and maintain a quality assurance program that ensures a clean and sanitary environment for the preparation of sterile products and insures that the parenteral products that are produced are sterile. Documentation of such activities shall be available.

(b) The quality assurance program shall include at least the following:

(1) Cleaning and sanitization of the parenteral medication preparation area;

(2) Surveillance of parenteral solutions for microbiological contamination and actions taken in the event that testing for contamination proves positive;

(3) Where bulk compounding of parenteral solutions is performed, the surveillance of parenteral solutions for microbiological contamination and pyrogens, and documentation of the results prior to dispensing to the patient;

(4) Periodic documentation of the room and refrigerator temperature in which compounded parenteral products are stored;

(5) Steps to be taken in the event of a drug recall; and

(6) Written justification of expiration dates for compounded parenteral products.

Ph 404.10 Reference Library.

(a) Pharmacies engaged in the practice of compounding and dispensing parenteral solutions shall have current reference materials located in or immediately available to the pharmacy.

(b) In addition to Ph 702.07 (a)(7)(8), such reference materials shall include information on:

(1) All drugs and chemicals used in parenteral therapy services; and

(2) All parenteral therapy manufacturing, dispensing, distribution and counseling services provided.

Ph 404.11 Compounding Location. All sterile pharmaceutical solutions and products compounded and distributed by licensed facilities located out of state shall be in compliance with Part Ph 404.

**Adopt Ph 405, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

PART Ph 405 STANDARDS OF PRACTICE FOR NUCLEAR/RADIOLOGIC PHARMACY

Ph 405.01 Purpose and Scope. The practice of nuclear pharmacy is hereby recognized as a specialty of pharmacy practice, regulated by the state board of pharmacy. As such, the following rules are included to address those areas specific or unique to this specialty practice. These rules shall supplement the rules/regulations of other state and federal agencies.

Ph 405.02 Definitions.

(a) "Authentication of product history" means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

(b) "Nuclear pharmacy" means a pharmacy which provides radiopharmaceutical services.

(c) "Practice of nuclear pharmacy" means a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs.

(d) "Quality assurance procedures" means all activities necessary to guarantee the integrity of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by the division of public health services, bureau of radiological health.

(e) "Quality control testing" means the performance of chemical, biological and physical tests on compounded radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.

(f) "Radiopharmaceutical" means any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons. The term includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term also includes any biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

(g) "Radiopharmaceutical service" means the procurement, storage, handling, compounding, preparation, labeling, quality control testing, dispensing, distribution, transfer, record keeping and disposal of radiochemicals, radiopharmaceuticals and ancillary drugs.

Ph 405.03 General Requirements for Pharmacies Providing Radiopharmaceutical Services.

(a) A permit to operate a pharmacy, which provides radiopharmaceutical services shall only be issued to a person who is, or who employs a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs shall be under the direct supervision of a qualified nuclear pharmacist, who shall be in personal attendance when the pharmacy is open for business. The pharmacist-in-charge shall be responsible for all operations of the pharmacy.

(b) The nuclear pharmacist who licenses the pharmacy shall hold a current license issued by the board, and shall be either certified as a nuclear pharmacist by the board of pharmaceutical specialties or shall satisfy each of the following requirements:

(1) Meets minimal standards of training for status as authorized user of radioactive material, as specified by the division of public health services, bureau of radiological health;

(2) Has successfully completed a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from a

nationally accredited college of pharmacy, or other training program recognized by the division of public health services, bureau of radiological health;

(3) The 200 hours of instruction referenced in (2) above shall be apportioned as follows:

a. Radiation physics and instrumentation, 85 hours;

b. Radiation protection, 45 hours;

c. Mathematics pertaining to the use and measurement of radioactivity, 20 hours;

d. Radiation biology, 20 hours; and

e. Radiopharmaceutical chemistry, 30 hours;

(4) Has attained a minimum of 500 hours of clinical/practical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in, but not limited to, the following areas:

a. Procuring radioactive materials;

b. Compounding radiopharmaceuticals;

c. Performing routine quality control procedures;

d. Dispensing radiopharmaceuticals;

e. Distributing radiopharmaceuticals;

f. Implementing basic radiation protection procedures; and

g. Consulting and educating the nuclear medicine community, patients, pharmacists, other health professionals, and the general public;

(5) Has submitted an affidavit of experience and training to the board.

(c) The permit to operate a nuclear pharmacy shall be effective only so long as the pharmacy also holds a current license issued by the division of public health services, bureau of radiological health. Copies of the bureau of radiological health inspection reports shall be available at the pharmacy for board inspection.

(d) Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided and meeting minimal space requirements established for all pharmacies in the state.

(e) All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas:

(1) Radiopharmaceutical preparation/dispensing area;

(2) Radioactive material shipping/receiving area;

(3) Radioactive material storage area; and

(4) Radioactive waste decay area.

(f) The application for a permit to operate a nuclear pharmacy shall be the same as in Ph 304.01 and Ph 304.02.

(g) The nuclear pharmacy professional service area shall be secured from unauthorized personnel and shall be totally enclosed and lockable.

(h) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radioactive drugs and other radioactive materials in accordance with the board and the division of public health services, bureau of radiological health statutes and rules.

(i) A radiopharmaceutical shall be dispensed only to a licensed practitioner authorized by the division of public health services, bureau of radiological health to possess, use and administer such drug. A radiopharmaceutical shall be dispensed only upon receipt of a prescription or medication order from such licensed practitioner. Otherwise, a radiopharmaceutical may be transferred to a person who is authorized to possess and use such drug for non-clinical applications.

(j) A nuclear pharmacy, upon receiving an oral prescription order for a radiopharmaceutical, shall immediately have the prescription order reduced to writing, or recorded in a data processing system.

(k) The writing or record required by (i) above shall contain at least the following:

(1) The name of the institution and prescriber, or prescribers' agent;

(2) The date of dispensing and the calibration time of the radiopharmaceutical;

(3) The name of the procedure;

(4) The name of the radiopharmaceutical;

(5) The dose or quantity of the radiopharmaceutical;

(6) The serial number assigned to the order for the radiopharmaceutical;

(7) Any specific instructions;

(8) The initials of the person who received the order; and

(9) The initials of the person who dispensed the order.

(l) Whenever an order is for a therapeutic or blood-product radiopharmaceutical, the patient's name shall be obtained and recorded prior to dispensing.

(m) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with:

(1) The name and address of the pharmacy;

(2) The name of the prescriber;

(3) The date of dispensing;

(4) The serial number assigned to the order for the radiopharmaceutical;

(5) The standard radiation symbol;

(6) The words "Caution Radioactive Material";

(7) The name of the procedure;

(8) The radionuclide and chemical form;

(9) The amount of radioactivity and the calibration date and time;

(10) If a liquid, the volume;

(11) If a solid, the number of items or weight;

(12) If a gas, the number of ampules or vials;

(13) Molybdenum 99 content to USP limits; and

(14) The name of the patient or the words "Physician's Use Only" in the absence of a patient name.

(n) When the prescription is for a therapeutic or blood-product radiopharmaceutical, the patient name shall appear on the label. The requirements of this sub-section shall be met when the name of the patient is readily retrievable from the physician upon demand.

(o) The immediate inner container label of a radiopharmaceutical to be dispensed shall be labeled with:

(1) The name of the pharmacy;

(2) The standard radiation symbol;

(3) The words "Caution Radioactive Material";

(4) The identity of the radionuclide;

(5) The chemical form;

(6) The name of the procedure; and

(7) Serial number of the radiopharmaceutical.

(p) When a radiopharmaceutical is dispensed under the authority of an investigational new drug application (IND), the nuclear pharmacy records shall include an investigator's protocol for the preparation of the radiopharmaceutical, and a letter from the manufacturer or sponsor indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

(q) Each nuclear pharmacy shall have a current copy of the United States Pharmacopeia/National Formulary (USP/NF), USP-DI, and a current copy of state and federal rules and regulations governing the safe storage, handling, use, dispensing, transport and disposal of radiopharmaceuticals.

Ph 405.04 Minimum Equipment. The pharmacy shall have at least the following equipment:

(a) A radionuclide dose calibrator;

(b) A refrigerator;

(c) A single or multiple channel scintillation counter with well-type NaI(Tl) or Ge(Li) detector;

(d) A radiochemical fume hood and filter system with air sampling equipment;

(e) An area survey meter;

(f) At least 2 GM survey meters including one high-range meter;

(g) A microscope and hemacytometer;

(h) A laminar air flow hood and appropriate supplies to ensure sterile practices for parenteral solutions;

(i) Syringe and vial radiation shields;

(j) A lead-shielded drawing station;

(k) Decontamination supplies;

(l) Supplies to perform quality assurance testing;

(m) Lead transport shields for syringes and vials; and

(n) New Hampshire department of transportation approved USA Type A - 7A approved transport containers and other labels and supplies for shipping radioactive materials.

**Adopt Ph 500, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

CHAPTER Ph 500 ETHICAL STANDARDS

PART Ph 501 CODE OF ETHICS

Ph 501.01 Standards of Conduct.

(a) The ethical standards set forth in this part shall bind all licensees, and violation of any such standard shall be a basis for the imposition of disciplinary sanctions.

(b) A licensed pharmacist shall:

(1) Hold the health and safety of patients to be of first consideration and render to each patient the full measure of his/her ability as an essential health practitioner;

(2) Never condone the dispensing, promoting or distributing of drugs or medical devices, or assist therein, which are not of good quality, which do not meet standards required by law or which lack therapeutic value for the patient;

(3) Always strive to perfect and enlarge his/her professional knowledge;

(4) Utilize and make available his/her knowledge as might be required in accordance with his/her best professional judgment;

(5) Observe the law, uphold the dignity and honor of the profession, and accept its ethical principles;

(6) Pharmacists shall not engage in any activity that will bring discredit to the profession and shall expose, without fear or favor, illegal or unethical conduct in the profession;

(7) Seek at all times only fair and reasonable remuneration for services rendered;

(8) Never agree to or participate in transactions with practitioners of other health professions or any other person under which fees are divided or which might cause financial or other exploitation in connection with the rendering of their professional services;

(9) Respect the confidential and personal nature of professional records, except in emergency situations where the best interest of the patient requires or the law demands, and shall not disclose such information to anyone without patient authorization;

(10) Not agree to practice under terms or conditions which tend to interfere with or impair the proper exercise of professional judgment and skill, which could tend to cause a deterioration of the quality of his/her service or which require him/her to consent to unethical conduct;

(11) Refrain from advertising professional services in a manner which is misleading to the public or which conveys by implication that the services of fellow pharmacists are unethical or inferior;

(12) Maintain a sanitary and orderly prescription department which is fully equipped and stocked to meet the needs of the community; and

(13) Fulfill all professional obligations conscientiously and with due respect for the physical and well-being of the community, and, uphold at all times the standards of the profession of pharmacy.

CHAPTER Ph 600 RESERVED

**Adopt Ph 701.01, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

CHAPTER Ph 700 STANDARDS OF PRACTICE

PART Ph 701 REFERENCES AND DEFINITIONS

Ph 701.01 Applicability. The provisions of this chapter shall apply to, and impose duties upon, all pharmacists, pharmacies, manufacturers, wholesalers and distributors holding licenses issued by the board.

**Amend Ph 701.02, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2/1/99 (Doc. #6933) and amended eff. 8-1-01 (Doc. #7535), by inserting Ph 701.02 (a), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 701.02 Definitions. Except where the context makes another meaning manifest, the following words mean:

(a) "Adulterated drug" means any drug:

(1) That is contaminated, decomposed, deteriorated, sub-potent, super-potent, or otherwise unsafe for administration to man or other animals;

(2) Which has been manufactured, composed, prepared, stored, or dispensed in such a manner which may cause it to be contaminated, decomposed, deteriorated, sub-potent, super-potent, or otherwise unsafe for administration to man or other animals;

(3) Whose labelled expiration date has been exceeded by more than 30 days; and

(4) Which can be defined as an adulterated drug under the provisions of RSA 146 or federal law.

**Adopt Ph 701.03, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 701.03 References. Persons subject to these rules shall comply with the following regulations and statutes as cited:

(a) RSA 146, the New Hampshire Public Health Law;

(b) RSA 318, the New Hampshire Pharmacy Act;

(c) RSA 318-B, the New Hampshire Controlled Drug Act;

(d) 21 USC Sections 321 through 374, the Federal Food, Drug, and Cosmetic Act;

(e) 21 CFR 1300 to end; and

(f) The United States Pharmacopeia.

**Adopt Ph 702.01 thru 702.04, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

PART Ph 702 PHARMACY FACILITIES AND EQUIPMENT

Ph 702.01 Area, Space and Fixtures.

(a) Pharmaceuticals, library and equipment shall be housed in a well lighted and ventilated room or department with clean and sanitary surroundings devoted primarily to the compounding of

prescriptions. This portion of a pharmacy shall have an area of not less than 200 square feet. No area shall be included in the calculation of the minimum area required by this section unless that area is used exclusively for the storage, manufacture, compounding, and dispensing of drugs.

(b) The space primarily devoted to the compounding of prescriptions shall be equipped with:

(1) Necessary counters and storage cabinets;

(2) A sink with hot and cold running water; and

(3) Refrigeration storage equipment used capacity exclusively for drugs.

(c) Upon written request by an institution the board shall waive minimum area requirements for institutional pharmacies upon a showing that the extent of pharmaceutical services provided does not require the full 200 square feet.

Ph 702.02 Temperature. The temperature in any area wherein drugs are stored, manufactured, compounded or dispensed, shall, at all times be in compliance with the standards established by the United States Pharmacopeia.

Ph 702.03 Quarantine. Any drug which is adulterated or misbranded shall be removed from routine stock and held in a specifically designated area of the pharmacy pending proper and safe disposition.

Ph 702.04 Security.

(a) That portion of a pharmacy wherein drugs are stored, manufactured, compounded or dispensed, shall, when the pharmacy is open, be so designed and constructed as to prevent entry into that area by any person or persons without the knowledge of the pharmacist then on duty, or when the pharmacy is not open to the public, by the activation of an alarm.

(b) The pharmacy shall be equipped with an alarm system which, when activated, shall emit a signal which is:

(1) Audible to the average person situated outside the building in which the pharmacy is located, at least 100 feet from any point of that building, or the public highway closest to that building, whichever is greater; or

(2) Observable by a law enforcement or security officer situated in a station of the law enforcement organization having jurisdiction over the area in which the pharmacy is located or in an office of a security organization serving the area in which the pharmacy is located.

(c) In order to be adequately designed and constructed, within the meaning of this section, a pharmacy shall be equipped with a door or doors capable of being locked.

**Amend Ph 702.05, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 702.05 (a) - (c), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 702.05 Limitations on Access.

(a) No pharmacy shall be open unless a pharmacist is on duty in the pharmacy. At all times during which a pharmacist is not on duty in the pharmacy, all entry to the pharmacy shall be barred by locked doors.

(b) The keys to the locked doors of a pharmacy shall be possessed only by:

(1) The pharmacist-in-charge;

(2) Pharmacists in the employ of the pharmacy;

(3) A non-pharmacist owner or owners of the pharmacy;

(4) Qualified security personnel as shall be designated by the pharmacist-in-charge and a list of such personnel shall be filed with the board by the pharmacist-in-charge; or

(5) If an institutional pharmacy, administrators of the institution and those nurses designated to enter the pharmacy to obtain medications in emergency situations.

(c) A non-pharmacist owner or owners may be on the premises of a pharmacy which he or she owns in the absence of a pharmacist employed by that pharmacy, provided that the pharmacy is not open and no drugs are compounded, dispensed or sold.

**Adopt Ph 702.06, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 702.06 Minimum Drug Standards. Registrants shall comply with the minimum drug standards set forth in the United States Pharmacopeia (USP).

**Adopt Ph 703.01 thru 703.05, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

PART Ph 703 RECORDS AND REPORTS

Ph 703.01 Recordkeeping Requirements. The requirements of Ph 703 shall be in addition to all record keeping and reporting requirements contained in all federal and state statutes and regulations.

Ph 703.02 Bulk Compounding.

(a) Each pharmacy shall maintain a series of records, separate from all other records, and used exclusively for the recording of data regarding compounding for direct patient dispensing of drugs.

(b) The pharmacist who compounds or supervises the compounding of prescription drugs in bulk, shall maintain a written record that contains at least the following information:

(1) The formula of the compound;

(2) The identity of the manufacturer of the bulk chemicals, the lot number and the expiration date of each ingredient contained in that formula;

(3) The assigned in-house, quality control lot number, date of compounding and an expiration date which shall not exceed 1 year; and

(4) The name or initials of the compounding pharmacist.

Ph 703.03 Prepackaging Of Drugs.

(a) Drugs shall be prepackaged in quantities suitable for internal distribution only by a pharmacist or by supportive personnel under the direct supervision of a pharmacist.

(b) The label of a prepackaged unit shall indicate the:

(1) Brand name and strength of the drug, or if no brand name, the generic name, strength, and name of the manufacturer or distributor;

(2) Assigned in-house, quality control lot number;

(3) Expiration date; and

(4) Quantity of the drug, if the quantity is greater than one.

(c) The pharmacist who prepackages or supervises prepackaging shall maintain a written record that contains at least the following information:

(1) Name of the drug, strength, and dosage form;

(2) Assigned in-house, quality control lot number;

(3) Manufacturer or distributor;

(4) Manufacturer's lot number;

(5) Expiration date;

(6) Quantity per prepackaged unit;

(7) Number of prepackaged units;

(8) Date packaged;

(9) Name or initials of the prepacker; and

(10) Signature of the responsible pharmacist.

(d) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

Ph 703.04 Controlled Drug Losses.

(a) The pharmacist-in-charge shall report to the board the loss or suspected loss of any controlled drug from his or her pharmacy. The pharmacist-in-charge shall notify the board by phone within 72 hours of the loss followed by a written report signed by the pharmacist-in-charge, on DEA Form 106, as set forth in 21 CFR 1301.76(b) and mailed to the board not later than 15 days after the pharmacist-in-charge discovered that controlled drugs were missing from his or her pharmacy.

(b) The written report referenced in (a) shall contain at least the following:

(1) Date of discovery;

(2) The identity of the person making the discovery;

(3) The name and location of the pharmacy from which the drug is missing; and

(4) The identity and quantity of the missing drug(s).

Ph 703.05 Automated Data Processing Systems. As an alternative to the procedures provided in RSA 318, RSA 318-B and these rules, an automated data processing system may be used for the storage of original prescriptions and the retrieval of refill information for all prescription orders including, but not limited to, controlled substances in schedules II, III, IV, and V, as defined in 21 CFR 1308.11-1308.15 subject to the following conditions:

(a) The system shall provide security against improper manipulation or alteration of stored records. Individual access codes shall be unique to each licensed location and shall not be available to any other location.

(b) A pharmacy shall make arrangements with the supplier of data processing services or materials to assure that the pharmacy continues to have access to the complete prescription and dispensing records if the relationship with such supplier terminates for any reason. A pharmacy shall assure continuity in the maintenance of records for the protection of public health.

(c) If an automated data processing system is used for the storage and retrieval of refill information for prescription orders as authorized by Ph 703.05, the pharmacy may use a traditional handwritten system only to satisfy the requirements of Ph 703.05(n) of the Code of Administrative Rules.

(d) Each pharmacist-in-charge of a licensed pharmacy which utilizes an automated data processing system shall comply with all provisions of this section.

(e) Any such proposed computerized system shall provide on-line retrieval, via CRT display or hard-copy printout, of all prescription records processed at that licensed location.

(f) The information required by (e) above shall include:

(1) The original prescription number;

(2) The date of issuance of the original prescription order by the practitioner;

(3) The full name and address of the patient;

(4) The name, address, and DEA registration number of the practitioner, when applicable; and

(5) The name, strength, dosage form, quantity prescribed, and quantity dispensed if different from the quantity prescribed, and the total number of refills authorized by the prescribing practitioner, if any.

(g) Any such proposed computerized system shall also provide on-line retrieval, via CRT display or hard-copy printout, of the current refill history of all prescription orders including controlled substances in schedules III, IV, and V.

(h) This refill history shall include:

(1) The name of the drug;

(2) The date of refill;

(3) The quantity dispensed;

(4) The identification code, or name or initials of the dispensing pharmacist for each refill; and

(5) The total number of refills dispensed to date for that prescription order.

(i) When filing refill information for original prescription orders for schedules III, IV, and V controlled substances, a pharmacy shall use only a computerized system or a non-computerized system.

(j) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order, including refill orders for a schedule III, IV, or V controlled substances is correct shall be provided by:

(1) A hard-copy printout of each day's controlled substance prescription order refill data which shall be verified, dated, and signed by each pharmacist who refilled such prescription orders; or

(2) In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown.

(k) The hard-copy printout and the log book referenced in (l) above shall be kept at the pharmacy, in a separate file, for a period of 4 years from the dispensing date.

(l) The computerized system shall have the capability of producing a printout of all refill data and shall include:

(1) A refill-by-refill audit trail for any specified strength and dosage form of any controlled substance;

(2) Name of the prescribing practitioner;

(3) Name and address of the patient;

(4) Quantity dispensed on each refill;

(5) Date of the dispensing for each refill;

(6) Name or identification code of the dispensing pharmacist; and

(7) The number of the original prescription order.

(m) In any computerized system employed by a user pharmacy, the central recordkeeping location shall be capable of sending the printout to the pharmacy within 48 hours.

(n) In the event that a pharmacy which employs such a computerized system experiences system down-time, the pharmacy shall have an auxiliary procedure which shall be used for documentation of all refills including authorized refills of schedules III, IV, and V controlled substance prescription orders. This auxiliary procedure shall ensure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again.

(o) Each pharmacy using an automated data processing system shall maintain on file a hard copy of all prescriptions preserving all information contained on the original written or oral prescription. Any computer generated material shall be affixed to the rear of the prescription, leaving the face of the prescription intact.

(p) Computer-produced prescription container labels shall comply with RSA 318:47 (a), RSA 318:47-b and RSA 318-B:13, II.

(q) Institutional pharmacies located in hospitals, clinics or nursing homes and providing pharmacy services for in-patients only, as well as providers of pharmaceutical services to institutions from an off-premise location and utilizing a unit dose drug distribution system, shall be exempt from the provisions of this rule provided that:

(1) The pharmacist-in-charge submits a written request for exemption to the board of pharmacy;

(2) Written policies and procedures detailing the drug distribution system are available at the institution for inspection; and

(3) The system provides for a simple, accurate, and timely audit trail for all controlled substances.

(r) In the event that a pharmacy using an electronic data processing system for storage and retrieval of prescription information goes out of business, sells out to another pharmacy that does not wish to use such a system, or discontinues use of the computer system, the seller pharmacy shall:

(1) Notify the board of pharmacy in writing at least 30 days prior to discontinuance of said system;

(2) Provide an up-to-date hard-copy printout of all non-controlled drug prescriptions stored in the automated system for one year and a printout of all controlled drug prescriptions for the current 2 year period as part of the final records of that pharmacy prior to a change over to a manual system; and

(3) Make provision for these records to be available to any nearby pharmacy in the event that the pharmacy closes, as provided in Ph 708.02.

**Adopt Ph 703.07, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 703.07 Inspection Report. The current compliance inspection report of the licensed location, conducted by the board, shall be posted conspicuously in the prescription department.

**Adopt Ph 704.02 thru 704.06, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 704.02 Pre-signed Prescription Blanks. No person shall possess, and no pharmacy shall have within it, any document signed by a prescriber which, if completed, would be usable as a prescription.

Ph 704.03 Transmission of Prescription Drug Order by Prescriber.

(a) A prescription drug order may be transmitted to a pharmacy by an authorized prescriber or his designated agent either in writing, orally or electronically.

(b) An electronically transmitted prescription drug order shall:

(1) Be sent to the pharmacy of the patient's choice; and

(2) Include the name and address of the practitioner, the practitioners phone number for verbal confirmation, the time and date of transmission and the name of the pharmacy intended to receive the transmission as well as any other information required by federal or state law.

(c) The pharmacist shall exercise professional judgment regarding the accuracy and authenticity of the electronically transmitted prescription drug order consistent with existing federal or state laws and rules.

(d) A prescription may be electronically transmitted to and received by a pharmacy provided that the identity of the prescriber and the transmitting agent is included in the order.

(e) For controlled substances in Schedules III, IV or V an electronically generated copy of a written, signed prescription transmitted directly by the prescribing practitioner, or the practitioner's agent, to the pharmacy, may be used as the original prescription.

(f) For controlled substances in Schedule II, a pharmacy may receive an electronically transmitted drug order directly from the prescriber for filling, provided however, that the original written prescription shall be presented and verified against the electronic record at the time the

substances are actually dispensed and that the original document shall be processed and retained for filing.

(g) There shall be 2 exceptions to the requirements stated in (f)above:

(1) Schedule II home infusion/intravenous (I.V.) pain therapy prescriptions may be electronically transmitted by the practitioner or the practitioner's agent to a pharmacy to be compounded for the direct administration to a patient in a private residence, long term care facility or hospice setting by means of parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion; and

(2) Schedule II prescriptions for patients in Long Term Care Facilities may be electronically transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy.

(h) In the case of (g)(1) above the electronic record shall serve as the original/written prescription and it shall comply with all federal and state laws, rules and regulations for Schedule II prescriptions. The exception shall not apply to oral dosage units.

(i) In the case of (g)(2) above the electronic record shall serve as the original/written prescription and it must comply with all federal and state laws, rules and regulations for Schedule II prescriptions.

(j) The device used for the receipt of electronically transmitted prescription drug orders shall be located in the prescription department of the pharmacy in order to protect patient confidentiality and to assure security.

Ph 704.04 Transfer of Prescriptions. Original prescription drug order information for noncontrolled drugs may be transferred between pharmacies for the purpose of refill dispensing subject to the following:

(a) The transfer shall be communicated directly between 2 licensed pharmacists;

(b) The transferring pharmacist shall:

(1) Write the word "VOID" on the face of the prescription;

(2) Note in the patient medication record that a copy has been issued, the date of transfer, and the name of the pharmacist transferring the prescription; and

(3) Record in the patient medication record the name and address of the pharmacy to which the prescription was transferred and the name of the pharmacist receiving the prescription information.

(c) When a prescription is transferred, no further refills shall be issued by the transferring pharmacy.

(d) The pharmacist receiving the transferred prescription information shall:

(1) Write the word "transfer" on the face of the transferred prescription;

(2) Provide all information required to be on the prescription including the:

a. Patient's name and address;

b. Doctor's name and address;

c. Date of issuance of original prescription;

d. Number of valid refills remaining and date of last refill;

e. Pharmacy name, address, and original prescription number from which the prescription information was transferred; and

f. Name of the transferor pharmacist.

(e) The pharmacist shall maintain both the original and transferred prescription as if they were original prescriptions.

(f) A transferred prescription may be refilled, without limitation, up to the number of remaining refills, as originally authorized, or up to one year from the date of original issue, whichever shall occur first.

(g) The transfer of original prescription drug order information for controlled substances listed in Schedule III, IV or V shall conform to the requirements of 21 CFR 1306.26 and shall be permissible between pharmacies on a one-time basis and shall not be further transferred.

(h) For noncontrolled drugs, 2 or more pharmacies may establish and use a common electronic file to maintain required dispensing information. Pharmacies using such a common electronic file shall not be required to physically transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file, except that any such common file shall contain complete and adequate records of such prescription and the date and location of each refill dispensed and provisions shall be made to assure that the number of authorized refills shall not be exceeded.

(i) Institutional pharmacies may receive and dispense electronically transmitted prescription drug orders for inpatients.

(j) A pharmacist may dispense original, inpatient prescription drug orders received by electronic transmission from a health care facility.

Ph 704.05 Schedule V Controlled Substances.

(a) A Schedule V drug which does not require a prescription as set forth in 21CFR 1306.15 and 21 CFR 1306.32 shall only be sold at retail without a prescription by a licensed pharmacist and not by a non-pharmacist employee even if under the direct supervision of a pharmacist. However, after the pharmacist has fulfilled his or her professional and legal responsibilities as set forth in this section, the cash/credit transaction or delivery may be completed by a non-pharmacist.

(b) A pharmacist shall exercise professional discretion in the sale of a Schedule V drug, as referenced in (a), to insure that the product is being sold for medical purposes only.

(c) A Schedule V drug, as referenced in (a), shall only be sold at retail without a prescription to a person at least 18 years of age. The pharmacist shall require every retail purchaser of a non-legend Schedule V product to furnish a suitable identification, including proof of age when appropriate, in order to purchase a non-legend Schedule V product. The name and address obtained from such identification shall be entered in the record of disposition to consumer.

(d) All cough syrups containing codeine shall not be dispensed without a prescription.

Ph 704.06 Drug Product Selection.

(a) Unless instructed otherwise by the person receiving the drug pursuant to the prescription, a pharmacist filling a prescription for a drug product prescribed by its trade or brand name may select a therapeutically equivalent drug product with the same established name, active ingredient, strength, quantity and dosage form as the drug product identified in the prescription.

(b) Therapeutically equivalent drugs shall include only those drug products listed in "Approved Prescription Drug Products with Therapeutic Equivalence Evaluations" published by the United States department of health and human services.

(c) The pharmacist shall not select an equivalent drug product if the prescriber handwrites "medically necessary" on the written prescription, or when ordering a prescription orally the prescriber specifies that the prescribed drug is medically necessary. The designation of "medically necessary" shall not be preprinted or stamped on the prescription. This paragraph shall not preclude a reminder of the procedure required to prohibit selection of an equivalent drug product from being preprinted on the prescription.

(d) The pharmacist shall not select an equivalent drug product unless its price to the purchaser is less than the price of the prescribed drug product.

(e) The pharmacist or the pharmacist's agent, assistant or employee shall inform the person receiving the drug pursuant to the prescription of the selection of a lower-cost equivalent drug product and of the person's right to refuse the product selected.

(f) Unless the prescriber instructs otherwise, the label for every drug product dispensed shall include the product's trade or brand name, if any, or its established generic name and the name of the manufacturer, packer or distributor, using abbreviations such as NDC number if necessary. In the interest of public health and safety, the pharmacist may, when dispensing a generic drug, include the brand name on the prescription label following the generic name. The brand name, however, shall be preceded or followed with the word "sub", indicating substituted for, or "I.C.",indicating interchanged for. There shall be no exceptions to this provision.

(g) The pharmacy file copy of every prescription shall include the trade or brand name, the name of the manufacturer, and the packer or distributor of the drug product dispensed.

**Amend Ph 704.07, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 704.07 (b), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 704.07 Return of Drugs and Devices.

(b) Exceptions to Ph 704.07 (a) shall include:

(1) Orthopedic appliances;

(2) Crutches;

(3) Canes;

(4) Wheelchairs;

(5) Hospital beds;

(6) Bed rails;

(7) Trapezes;

(8) Other durable equipment that can be properly sanitized; and

(9) Medications dispensed in unit-dose packaging to institutionalized patients.

**Adopt Ph 704.08 thru 704.13, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 704.08 Prescription Pick-up and Delivery.

(a) No person licensed under the provisions of RSA 318, shall enter into or participate in any arrangement or agreement whereby prescriptions may be left at, picked up from, accepted by, or delivered to any store, shop or location not licensed as a pharmacy.

(b) This section shall not prohibit a licensee from picking up prescriptions or delivering prescribed medications at the residence of the patient, or directly to the patient at his/her workplace, or at the institution in which the patient is confined, by means of an employee or by use of a common carrier.

Ph 704.09 Dispensing Adulterated or Misbranded Drugs. A pharmacist shall not dispense or sell to the public any drug which is adulterated or misbranded. After notice and opportunity for a hearing, a pharmacist who is found by the board to have knowingly dispensed or otherwise sold for consumption an adulterated or misbranded drug, shall be subject to disciplinary action according to RSA 318:29.

Ph 704.10 Out-of-State Prescriptions. Prescriptions written by physicians in a state other than New Hampshire may be dispensed to a patient only when the traditional physician-pharmacist-patient relationship exists.

Ph 704.11 Pharmacist-in-Charge Requirements/Duties.

(a) The pharmacist-in-charge or the pharmacist on duty shall control all aspects of the practice of pharmacy.

(b) The pharmacist-in-charge shall be responsible for the control of all drugs issued or dispensed in the pharmacy where he/she practices as well as:

(1) Establishing written policies and procedures for the procurement, storage, compounding, and dispensing of drugs;

(2) Ensuring that all staff pharmacists are familiar with and in compliance with the established policies and procedures;

(3) Supervising personnel in the prescription department;

(4) Establishing and supervising the recordkeeping system for the purchase, sale, possession, storage, and repackaging of drugs;

(5) Maintaining the security of the prescription department and its contents;

(6) Determining who will have keys and access to the pharmacy;

(7) Ensuring the medication dispensed is in conformance with the prescription received;

(8) Prohibiting the presence of misbranded drugs in the pharmacy; and

(9) Ensuring compliance with the provisions of the New Hampshire state pharmacy act, the New Hampshire state controlled drug act, any other state or federal pharmacy-related laws or rules.

(c) A pharmacist may serve as a pharmacist-in-charge for a maximum of 2 pharmacies, providing that one of these pharmacies shall be in an institution requiring the services of a pharmacist only on a part-time basis.

Ph 704.12 Termination of Pharmacist-in-Charge Notice. Whenever a pharmacist-in-charge shall cease performing that function, that pharmacist-in-charge shall notify the board in writing of the date upon which the cessation of that function is effective. That pharmacist-in-charge shall remain responsible for compliance, in the pharmacy in which he or she was the pharmacist-in-charge, with all pharmacy-related statutes and rules until the effective date of termination.

Ph 704.13 Termination of Pharmacist-in-Charge - Inventory. Whenever a pharmacist-in-charge shall cease performing that function in a pharmacy, the new pharmacist-in-charge shall, within 3 days, cause to be completed a written inventory of all controlled substances located in that pharmacy. The record of that inventory shall be retained in the pharmacy for a minimum of 4 years.

**Amend Ph 704.14, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 704.14 (a) and (b), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 704.14 Prescription Refill Limitations.

(a) Prescriptions bearing "PRN", "Ad lib" or other similar prescription refill designation permitting the pharmacist to refill the prescription as needed by the patient, shall be refilled only in keeping with the number of doses ordered and according to the directions for use, and in no instance shall such prescription be refilled beyond one year from the date of issue. If additional medication is needed thereafter, the original prescription shall be voided and a new prescription obtained.

(b) No prescription containing either specific or "PRN" refill authorization shall be refilled after the prescribing practitioner ceases to practice:

(1) Due to license suspension or revocation;

(2) If he/she no longer maintains a valid NH license;

(3) If prescribing limitations are placed on a practitioner's license by any state or federal licensing agency which impact on certain previously refillable prescriptions; or

(4) Due to death.

**Amend Ph 704.15, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 704.15 (a), (b), (d) and (e), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

(a) A failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

(b) Either:

(1) A natural or man-made disaster has occurred which prohibits the pharmacist from being able to contact the practitioner; or

(2) The pharmacist is unable to contact the practitioner;

(d) The pharmacist informs the patient or the patient's agent at the time of dispensing that the interim supply shall be final and that authorization by the practitioner shall be required for future refills; and

(e) The pharmacist shall inform the prescribing practitioner of the limited emergency supply, provided to the patient, at the earliest reasonable time.

**Adopt Ph 704.16, previously eff. 2-5-96, (Doc. #6181-B) and expired 2-5-04, to read as follows:**

Ph 704.16 Acts Prohibited. Splitting fees, making rebates, or sharing money received for pharmaceutical services, or the donation of and/or the use of equipment with other health practitioners or with health institutions providing patient care shall be deemed by the board to be contrary to the best interests of the patient, and shall therefore be prohibited.

**Adopt Ph 705.01 and Ph 705.02, previously eff. 2-5-96, (Doc. #6181-B) and expired 2-5-04, to read as follows:**

PART Ph 705 STORAGE OF DRUGS

Ph 705.01 Temperature. All drugs shall, at all times, be stored at a temperature which complies with the standards established by the current volume of the United States Pharmacopeia.

Ph 705.02 Prescription Drugs. All prescription drugs shall be stored in an area which is under the immediate control of a pharmacist and not accessible to unauthorized persons.

**Amend Ph 705.03, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 705.03 (a) – (d), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 705.03 Emergency Drug Kits for Long Term Care Facilities/Specialized Care Facilities.

(a) "Emergency drug kit" means a select supply of drugs and/or biologicals located at the licensed institution for the immediate administration to patients/residents upon the order of a practitioner as set forth in rules adopted under RSA 151.

(b) Emergency drug kits are allowed as set forth in rules adopted under RSA 151.

(c) Non-controlled legend drugs may be stored in the emergency drug kit as deemed necessary and jointly approved by the pharmacist, medical director and the director of nursing services.

(d) The placement of controlled substances in emergency drug kits in non-federally registered long term care facilities/specialized care facilities shall be deemed to be in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970 provided that:

(1) Controlled substances shall be stored in the emergency drug kit as deemed necessary and jointly approved by the pharmacist, medical director and the director of nursing services;

(2) The source from which controlled substances for emergency drug kits are obtained shall be a DEA registered hospital, clinic, pharmacy or practitioner;

(3) Controlled substances in emergency drug kits shall be limited to a maximum of 8 separate drug entities with not more than 8 single-use containers of each drug entity;

(4) The emergency drug kit containing controlled substances shall be closed with a tamper proof seal and kept in a locked medication room, cart or closet;

(5) Only the director of nursing services, registered nurse on duty, licensed practical nurse on duty, pharmacist or practitioner shall have access to controlled substances stored in an emergency drug kit;

(6) Controlled substances in emergency drug kits shall be administered to patients only by authorized personnel and only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 CFR 1306.11 and 1306.21;

(7) A usage record shall be contained in the emergency drug kit for each separate drug included which shall be completed by the nursing staff when using any controlled substance or substances from the kit;

(8) The pharmacist shall receive and file for 4 years a copy of all completed usage records;

(9) When the emergency drug kit is opened:

a. The pharmacist shall be notified by the facility within 24 hours; and

b. Shift counts shall be done by the nursing staff on all controlled substances until resealed by the consultant pharmacist.

(10) Shift counts of the controlled substances contained in the emergency kit shall not be required when the kit is sealed;

(11) The pharmacist shall check the controlled substances in the emergency drug kit at least monthly and so document inside the kit;

(12) The placement of controlled substances in emergency drug kits shall be only upon the written authorization of the board of pharmacy.

**Adopt Ph 706, previously eff. 2-5-96, (Doc. #6181-B) and expired 2-5-04, to read as follows:**

PART Ph 706 PHARMACEUTICAL CARE STANDARDS

Ph 706.01 Patient Records.

(a) A patient record system shall be maintained by all pharmacies for patients for whom prescriptions are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription is presented for dispensing.

(b) The pharmacist or supportive personnel shall make a reasonable effort to obtain, record, and maintain the following information:

(1) The full name of the patient for whom the drug is intended;

(2) The address and telephone number of the patient;

(3) The patient's age or date of birth;

(4) The patient's gender;

(5) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record during the 12 months immediately preceding the most recent entry showing:

a. The name of the drug or device;

b. The prescription number;

c. The name and strength of the drug;

d. The quantity and date received; and

e. The name of the prescriber; and

(6) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(c) The pharmacist shall make a reasonable effort to obtain from the patient or the patient's agent, and shall record, any known:

(1) Allergies;

(2) Drug reactions;

(3) Idiosyncrasies;

(4) Chronic conditions or disease states of the patient; and

(5) Usage of other drugs, including over-the-counter drugs, or medical devices currently being used by the patient.

(d) A patient record shall be maintained for a period of not less than 12 months from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

Ph 706.02 Prospective Drug Review.

(a) A pharmacist shall review the patient record and each prescription presented for dispensing for purposes of identifying:

(1) Over-utilization or under-utilization;

(2) Therapeutic duplication;

(3) Drug-disease contraindication;

(4) Drug-drug interactions;

(5) Incorrect drug dosage or duration of drug treatment;

(6) Drug-allergy interactions; and

(7) Clinical abuse or misuse.

(b) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem which might include consultation with the prescriber.

Ph 706.03 Patient Counseling.

(a) Upon receipt or delivery of a new prescription and following a review of the patient's record, a pharmacist or his/her designee, shall orally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of such patient.

(b) Patient counseling shall be by the pharmacist and in person, whenever practicable, or by telephone and shall include appropriate elements of patient counseling, such as the following:

(1) The name and description of the drug;

(2) The dosage form, dose, route of administration, and duration of drug therapy;

(3) Intended use of the drug and expected action;

(4) Special directions and precautions for preparation, administration, and use by the patient;

(5) Common side or adverse effects or interactions and therapeutic contraindications that might be encountered, including their avoidance, and the action required if they occur;

(6) Techniques for self-monitoring drug therapy;

(7) Proper storage;

(8) Prescription refill information;

(9) Action to be taken in the event of a missed dose; and

(10) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(c) Alternative forms of patient information may be used to supplement patient counseling. Examples shall include written information leaflets, pictogram labels, or video programs.

(d) Patient counseling, as described above shall not be required for inpatients of penal institutions or inpatients of a hospital or long term care facility where other licensed health care professionals are authorized to administer the drugs and drug therapy reviews are conducted on a routine basis

(e) Prospective drug use review, retrospective drug use review, and patient counseling shall be required for drugs dispensed by:

(1) Health maintenance organizations (HMO's);

(2) Mail order pharmacies;

(3) Hospital pharmacies providing outpatient prescription services; and

(4) Inpatients who are discharged with drugs.

(f) A pharmacist shall not be required to counsel a patient or agent when the patient or agent refuses such consultation. However, failure to document the patient's refusal of counseling shall imply that counseling was provided.

**Adopt Ph 707.01, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

PART Ph 707 DISPOSAL AND DESTRUCTION OF CONTROLLED DRUGS

Ph 707.01 Controlled Drug Destruction. Any person authorized to possess controlled drugs and desiring to dispose of such drugs may request destruction of the drugs by the board.

**Amend Ph 707.02, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 707.02 (a), (b) (2) – (7), (c), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 707.02 Request for Destruction.

(a) A request to destroy controlled drugs shall be in writing and signed by a duly authorized person as defined in (b) below. The written request may be presented to a board representative on site, but the destruction process shall not proceed until the board representative has the written request in his or her possession.

(b) Personnel authorized to sign a request for controlled drug destruction may include:

(2) Administrators of health care institutions or their designated agent or agents;

(3) Agents of the superior court;

(4) County attorneys;

(5) Director, New Hampshire state police;

(6) Chiefs of local police departments; and

(7) Director, New Hampshire division of public health services or his/her designated agent(s).

(c) The written request shall not be required when a consultant pharmacist, acting as an agent of the pharmacy board, destroys controlled drugs in a licensed nursing home.

**Amend Ph 707.03, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 707.03 (c) and (d), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 707.03 Board Authorized Controlled Drug Destruction.

(c) In the interest of the health and safety of group home residents, the facility's consultant pharmacist(s) may remove from such group homes any discontinued, expired or otherwise unusable drugs.

(d) In order to remove the drugs referenced in (c) above, the consultant pharmacist shall:

(1) Notify the board that a request has been made by the facility, to the consultant pharmacist, for removal of drugs;

(2) Submit to the board a written request for removal of such drugs;

(3) File one copy of form Ph 516 at the group home;

(4) Retain one copy with the drugs, which shall be removed to the consultant's place of practice; and

(5) Upon receipt of the original, a compliance investigator shall proceed to the consultant's place of practice to supervise the destruction of the drug.

**Adopt Ph 707.04, previously eff. 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 707.04 Controlled Drug Destruction by the Board of Pharmacy.

(a) The destruction of controlled drugs by the board shall occur on the premises of the practitioner, institution or agency requesting the destruction. However, agents of the board shall remove from the premises any drug or drugs for destruction to be disposed of by incineration. Destruction shall be carried out by any person so designated as the authorized agent of the board provided that such agent as well as the person requesting destruction or his or her designee are present during the entire destruction process.

(b) The practitioner or person requesting destruction or their designee shall also be present and shall witness destruction of the controlled drugs.

(c) Witnesses may include:

(1) The practitioner, including a pharmacist;

(2) The administrator or assistant administrator;

(3) The director of nursing, nursing supervisor or charge nurse;

(4) An agent of the court;

(5) A law enforcement officer;

(6) The Director, New Hampshire division of public health services or his or her designated agent or agents; and

(7) A county attorney.

**Amend Ph 707.05, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 707.05 (a), (b), and (d), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 707.05 Record of Controlled Drug Destruction.

(a) A record of the drugs destroyed shall be made on federal form DEA-4l, "Registrant's Inventory of Drugs Surrendered" in accordance with 21 CFR 1307.21, 22. This form may be obtained from the board office, identified in Ph 103.03 or from an office of the Drug Enforcement Administration.

(b) The data recorded on form DEA-41 shall include at least the:

(1) Name, strength, and quantity of the drugs destroyed;

(2) Date, time and place of destruction;

(3) Manner of destruction; and

(4) Signature and title of persons destroying and witnessing destruction of the controlled drugs.

(d) A copy of the record of those drugs destroyed shall be maintained on the premises where the destruction occurred for a period of 4 years.

**Adopt Ph 707.06, previously eff. 2-5-96 (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 707.06 Exemption. Nothing contained in part Ph 707 shall require the board to destroy any drug if the board determines that to do so would impair law enforcement efforts or the health or safety of any person.

**Adopt Ph 708.01, previously eff. 2-5-96 (Doc. #6181-B), and expired 2-5-04, to read as follows:**

PART Ph 708 TERMINATION OF A PHARMACY OPERATION

Ph 708.01 Notification of Closing.

(a) Written notification to the board shall be filed at least 15 days prior to the date of the anticipated closing. This notice shall indicate the date of closing and the planned disposition of legend drugs including controlled substances and all records thereof.

(b) Written notification to DEA shall be filed at least 15 days prior to the date of the anticipated closing. Compliance with DEA instructions relative to closing procedures shall be required.

(c) At least 5 days prior to the anticipated closing a notice shall be conspicuously posted at the pharmacy indicating the date of closing and the future location of the prescription files. This notice shall be posted for a period of at least 30 days unless removed by the landlord or a new tenant.

**Amend Ph 708.02, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 708.02 (a), (b), (c) (1) – (2), (e) previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 708.02 Disposition of Drugs/Records.

(a) Security of the pharmacy shall be maintained while there is a supply of legend drugs including controlled substances on the pharmacy premises. Stable, unopened containers of legend drugs including controlled drugs may be returned to the wholesaler/manufacturer for credit.

(b) At the time of closing, the remaining supply of non-controlled prescription drugs may be sold or given to another pharmacy.

(c) At the time of closing, the remaining supply of controlled substances may be sold or given to another pharmacy provided that:

(1) The transfer of schedule II substances shall comply with 21 CFR 1307.14 and 21 CFR 1305.06 by means of a properly executed federal DEA #222 Form;

(2) The transfer of schedules III, IV, and V are made by invoice with copies to each party and the board; and

(e) Before disposing of any merchandise in the pharmacy, the owner and pharmacist-in-charge shall submit the licensed premises to an inspection by a representative of the board to certify that all prescription drugs including controlled substances have been secured.

**Adopt Ph 708.03, previously eff. 2-5-96 (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 708.03 Final Written Report. No later than 20 days after a pharmacy closing, the licensee shall:

(1) Return the pharmacy permit to the board;

(2) Notify the board that all signs and symbols indicating the presence of a pharmacy have been removed;

(3) Notify the board that all labels and blank prescriptions have been destroyed;

(4) Notify the board that the DEA license and all blank DEA #222 forms have been returned to the regional director of the DEA;

(5) File with the board, a copy of the dated inventory of all controlled substances transferred including the name and address of the person(s) to whom these drugs and applicable records were transferred; and

(6) In the case of an involuntary closing, file with the board the final disposition of the drugs as soon as possible after the transfer is made.

**Adopt Ph 709.01, previously eff. 2-5-96 (Doc. #6181-B), and expired 2-5-04, to read as follows:**

PART Ph 709 INSTITUTIONAL PRACTICES

Ph 709.01 Definitions.

(a) "Satellite pharmacy" means a pharmacy in an institutional setting under the direction of a licensed pharmacist, that is remote from the centrally licensed pharmacy, but within the same

facility/location and dependent upon the centrally licensed pharmacy for administrative control, staffing and drug procurement.

**Amend Ph 709.02, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 709.02 (a), (b), (d), (e), and (f), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 709.02 Licensing and Practice Standards.

(a) A pharmacy permit shall be required for each institution with an on-premise pharmacy. Such permit shall be issued to a pharmacist-in-charge, who shall be licensed in the state of New Hampshire. When an institution procures prescription drugs for its patients only on individual prescriptions for specific patients from an off-premise licensed pharmacy, the institution shall not be required to obtain a pharmacy permit.

(b) If an institution does not have a pharmacy on its premises, it may enter into an agreement with a pharmacy licensed to provide such services. Such agreement shall be in writing and shall state the policy and procedures as required by Ph 709. A copy of the agreement shall be made available by the consultant pharmacist to the board upon request. The consultant pharmacist shall be responsible for the maintenance of all records and the compliance with state and federal laws and rules governing the practice of pharmacy.

(d) Satellite pharmacies located in an institution shall:

(1) Function under the central pharmacy license; and

(2) Be mobile or stationary and lockable so as to prevent access by unauthorized personnel.

(e) Members of the board and/or their agents shall inspect the pharmacy, drug room/medication room and all areas or departments of the facility where drugs are stored, manufactured, compounded, dispensed or distributed to ensure:

(1) That adequate drug security and storage requirements are met;

(2) That proper records are maintained; and

(3) That the facility is in compliance with all local, state and federal drug and pharmacy laws and rules.

(f) Those facilities obtaining prescription drugs only on individual prescriptions for specific patients from an off-premise licensed pharmacy shall not be exempt from inspection.

**Adopt Ph 709.03 thru 709.06, previously eff. 2-5-96 (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 709.03 Environment.

(a) The institutional pharmacy shall be enclosed, lockable and alarmed;

(b) The institutional pharmacy shall have adequate space necessary for the storage, compounding, labelling, dispensing and sterile preparation of drugs prepared in the pharmacy.

(c) The institutional pharmacy shall be arranged in an orderly fashion and shall be kept clean.

(d) A sink with hot and cold running water shall be available to all pharmacy personnel.

(e) The institutional pharmacy shall have locked storage for schedule II controlled substances and other controlled drugs requiring additional security.

(f) The institutional pharmacy shall have designated areas for the storage of flammable and caustic materials. Such areas shall meet the requirements set by local and state fire laws.

(g) The institutional pharmacy shall have a designated area for the laminar air flow hood for the preparation of sterile products.

Ph 709.04 Drug Security.

(a) Drugs stored in any area or department of the facility shall be plainly labelled and kept in a specifically designated, well-illuminated cabinet, closet or storage area and shall be accessible only to authorized personnel.

(b) When controlled drugs are stored in authorized areas other than in the pharmacy, special locked storage for all controlled substances requiring additional security shall be used.

(c) A pharmacist or supportive personnel under the direction of a pharmacist shall visit, at least monthly, all areas or departments of the institution where drugs, biologicals, pharmaceutical chemicals or other pharmaceutical preparations are stored to ensure that they are properly labelled, have not reached their expiration date and show no signs of deterioration. Any substance not conforming to these standards shall be removed from stock.

(d) A written record of each monthly inspection specified in (c) above shall be maintained and shall be available to the board upon request.

(e) The pharmacist shall ensure that the areas specified in (c) above are in compliance with federal and state drug laws relative to security, drug distribution and product tampering.

(f) The pharmacist-in-charge shall develop a distribution system which shall prevent drug diversion. When applicable, the inventory of all schedule II controlled substances and other controlled drugs as required by local, state and federal law stored in any area or department of the facility except the pharmacy shall be checked by 2 persons at least every 24 hours and accountability records shall be maintained.

Ph 709.05 Dispensing Practices.

(a) Drugs shall be dispensed only by or in the presence of and under the supervision of a pharmacist, physician, dentist, optometrist or advanced registered nurse practitioner in compliance with local, State and federal pharmacy-related laws and rules. Except upon the written order of a physician, dentist, optometrist or advanced registered nurse practitioner, a nurse may leave a properly labelled container of any non-controlled drug at the patient's bedside. A licensed nurse shall not dispense or compound drugs except as permitted by RSA 318:42.

(b) Whenever feasible, the pharmacy shall dispense medications from the original or direct copy of the prescriber's written order. Drugs shall be provided to patients in institutions only on the order of a practitioner legally authorized to write prescriptions. No change in the order for drugs shall be made without the approval of a practitioner qualified to write prescriptions.

(c) Each order pursuant to (b) above shall include at least the:

(1) Patient's name and location;

(2) Date of the order;

(3) Name and dosage of the drug;

(4) Directions; and

(5) Signature of the prescriber or nurse copying the order.

(d) Written policies and procedures shall be adopted which establish the method utilized in the procurement, storage and distribution of drugs in all areas or departments of the facility, and which are consistent with state and federal pharmacy laws and rules.

Ph 709.06 Access to the Pharmacy.

(a) Only a pharmacist shall have access to the pharmacy and its drug supplies. However, this shall not preclude the use of supportive personnel, approved by the pharmacist-in-charge, from being present in the pharmacy provided that the pharmacist is in the institution. The pharmacist-in-charge of each institutional pharmacy shall establish written policies identifying specific situations when

pharmacy supportive personnel may be present in the pharmacy in the absence of a licensed pharmacist.

(b) In the absence of a pharmacist and in accordance with RSA 318:38I licensed nurses, designated for this purpose by the pharmacist-in-charge, may obtain from the pharmacy or night cabinet such drugs as needed in an emergency when these drugs are not available in floor stock supplies.

(c) The authorized nurse may enter the pharmacy area and remove the following:

(1) A drug in its original container or a drug prepackaged for use within the facility subject to these rules; or

(2) An emergency supply of a drug from the original container to be administered to a specific patient.

(d) The authorized nurse shall leave a direct copy of the physician's order in the pharmacy or night cabinet and on a suitable form record the following:

(1) Name and strength of the drug taken;

(2) Dosage form taken;

(3) Quantity taken;

(4) Time and date of withdrawal;

(5) Patient name and/or location, where applicable;

(6) Nurse's signature.

(e) The nurse shall leave with the record the bulk container from which the medication was taken or a representative sample of the unit-dose medication.

**Amend Ph 709.07, eff. 2-5-96, (Doc. #6181-B), as amended eff. 2-1-99 (Doc. #6933), by inserting Ph 709.07 (b), previously effective 2-5-96, (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 709.07 Drug Control in Ambulatory Patient Treatment Areas.

(b) If a licensed pharmacist is on the premises, that pharmacist may fill one time, full amount, non-refillable prescriptions for patients for medications related to the ambulatory patient treatment visit.

**Adopt Ph 709.08 and 709.09, previously eff. 2-5-96 (Doc. #6181-B), and expired 2-5-04, to read as follows:**

Ph 709.08 Investigational Drugs. Investigational drugs shall be used only under the direct supervision of the principal investigator and shall be approved by an appropriate medical staff committee. Such drugs shall be stored in the pharmacy and shall be properly labelled. A central unit, which may be the pharmacy, shall be established where essential information on investigational drugs is maintained. Nurses shall be given basic pharmacologic information about the drug before administering.

Ph 709.09 Purchase of Drugs.

(a) The pharmacist-in-charge, with the consent of the institution's pharmacy and therapeutics committee or comparable committee of its medical staff shall be responsible for the quality of all drugs, biologicals and pharmaceutical chemicals.

(b) Purchasing of drugs, pharmaceuticals, biologicals, intravenous and irrigation fluids shall be subject to approval of the pharmacist-in-charge with the consent of the institution's pharmacy and therapeutic committee or comparable committee of its medical staff.

(c) Radiopharmaceuticals, blood and blood products, radiopaque media and medical devices may be exempted from the approval and/or control of the pharmacist-in-charge by the institution's pharmacy and therapeutics committee.

**Adopt Ph 710.01 and 710.02, previously eff. 2-5-96 (Doc. #6181-B), and expired 2-5-04, to read as follows:**

PART Ph 710 ADMINISTRATIVE FINES

Ph 710.01 Liability for Administrative Fines. Persons subject to the disciplinary authority of the board and other persons subject to administrative fines or penalties under RSA 318:29, IV may, after notice and an opportunity to be heard, be assessed fines or penalties in addition to, or in lieu of, other sanctions authorized under RSA 318:29, IV.

Ph 710.02 Severity of Fine.

(a) The decision to impose a fine and the amount of such fine shall depend on:

(1) The severity of harm to the public posed by the violation(s);

(2) The number of concurrent and/or repeated violations; and

(3) The frequency of violations committed by the particular licensee, permit holder, or other person.

(b) When no violation of the same type has occurred within the 5 years preceding the board's notice to the respondent, the fine assessed shall not exceed $1,000 per violation upon the licensee and/or $2,000 per violation upon the permit holder.

(c) When a single disciplinary infraction of the same type has occurred within the five years preceding the board's notice to the licensee, the fine assessed shall not exceed $2,000 per violation upon the licensee and/or $3,000 per violation upon the permit holder.

(d) When more than one disciplinary infraction of the same type has occurred within the 5 years preceding the board's notice to the licensee, the fine assessed shall not exceed $3,000 per violation upon the licensee and/or $5,000 per violation upon the permit holder.

(e) In the case of continuing violations, a separate fine shall be assessed for each day the violation continues, but the total amount of the fine and the licensee's promptness and cooperativeness in ceasing the prohibited conduct in question shall be considered in assessing the daily fines.

(f) In all cases, the board shall consider:

(1) The nature of the offense;

(2) The purpose of the rule or statute violated;

(3) The licensee's state of mind at the time the offense occurred;

(4) The potential harm to the public health;

(5) The deterrent effect upon other practitioners;

(6) The licensee's willingness to cooperate with the board;

(7) The cost to the board of any formal disciplinary hearings which were necessary;

(8) The licensee's acknowledgment of his or her wrongdoing; and

(9) The nature of any other disciplinary sanctions imposed as a result of the offense in question.